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Tissue Bank Visibility Could Be Improved By Centralized Listing Of Resources: Panel

Breast cancer tissue is being collected by tissue banks throughout the US. However, a researcher has no way to find a directory of those banks or learn what they contain.

A panel of experts convened by NCI last week recommended that a central library listing all available tissue banks be compiled in order to assess the scientists' needs for tissue in their research.

The library should be established before the launch of any national

(Continued to page 2)

Fisher, Interim NSABP Leadership Enter Third Day Of Negotiations To Settle Suit, Avert Court Battle

PITTSBURGH, Sept. 27—With the chief federal judge in Pittsburgh acting as determined mediator and his courtroom the staging area for a dozen attorneys over two days, Bernard Fisher's legal actions against the Univ. of Pittsburgh and the interim leadership of the National Surgical Adjuvant Breast & Bowel Project remained in limbo today.

Both sides were scheduled to begin arguments Sept. 26 before U.S. District Judge Donald Ziegler on Fisher's motion for an injunction seeking his immediate reinstatement as NSABP Chairman and the removal of the NSABP interim leadership.

However, attorneys for both sides agreed to leave their briefcases in the courtroom and take their clients into separate conference rooms for what turned into more than two full days of talks.

"This has all been very tiring and, frankly, we would like to see a resolution one way or the other," said Lewis Popper, general counsel for the Univ. of Pittsburgh. "I can say that the time for talking is running out. There will be either a settlement tomorrow or we will go ahead with a hearing."

Popper made the comment at the end of today's bargaining session as he escorted NSABP interim chairman Ronald Herberman out of the courtroom. The marathon discussions were a continuation of a round of talks that began in Ziegler's chambers during a "conciliation conference" two weeks ago.

Fisher filed the motion for an injunction against university officials Aug. 8, charging that the interim leaders were "undermining and destroying" the project, which he co-founded and led for more than 30 years.

--By Doug Root

Central Tissue Bank Library Proposed By NCI Ad Hoc Panel

(Continued from page 1)

effort to collect larger amounts of biological materials, the ad hoc panel convened by the NCI Div. of Cancer Biology, Diagnosis & Centers recommended.

The establishment of "comprehensive patient data registries and materials banks" to foster research was among top research priorities outlined by the National Action Plan on Breast Cancer last March (**The Cancer Letter**, Jan. 7 and March 25).

The meeting last week was convened to review the existing resources for biological materials related to breast cancer research and to discuss issues of informed consent, confidentiality, and access to materials.

"At this point, it was felt that we have a large number of resources that people just don't know about or know how to get access to," said Sheila Taube, chief of the NCI Cancer Diagnosis Branch, in the Div. of Cancer Biology, Diagnosis and Centers. "There needs to be a 'mother of all databases.'"

The proposed database library would list what tissue and resources are available and who is eligible for access to the resources.

"In some cases, there might be a significant amount of direct information so that researchers can have an idea of what is really available, and not have to call the resource itself," Taube said to **The Cancer Letter**.

The panel said the proposed library should have a board to monitor the listing of resources and help in planning and evaluation.

The board should monitor the research questions being asked to determine whether the available resources are meeting the needs of the scientific community.

Advisory To National Action Plan

In remarks prior to the meeting, Susan Blumenthal, deputy assistant secretary of health, said the NCI panel's conclusions will be advisory to the Institute and to the National Action Plan working group on patient data and resources, one of six working groups that grew out of the Shalala meeting. The resources working group is chaired by Susan Love, director of the Breast Center at the Univ. of California, Los Angeles.

Blumenthal and Fran Visco, president of the National Breast Cancer Coalition and a member of the President's Cancer Panel, are co-chairs of the National Action Plan.

"Breast cancer is of the highest priority of my office, the wider Public Health Service and the Clinton Administration," Blumenthal said. The National Action Plan "is not a federal plan, it is a national plan" involving patients, consumer advocates, and industry as well as federal agencies, she said.

Panel Recommendations

In its recommendations, the NCI panel emphasized the importance of informed consent for prospective studies, particularly in heritable breast cancer.

The panel recommended that:

- For retrospective studies, researchers should separate studies of heritable diseases from those not related to heredity. Institutional review boards could waive the need for informed consent in the case of studies not related to heredity, such as studies of prognosis and markers.
- For studies of heritable diseases in retrospective studies, the IRB could waive consent if the tissues were used in way that made it impossible to identify the individuals who donated the tissue.
- For prospective collections, informed consent for research use of tissues is appropriate and encouraged, but there should be a reasonable period of time for implementation.
- Re-consent should be obtained for prospective studies in heritable diseases.

The panel, chaired by Helene Brown, associate director for community research, Univ. of California, Los Angeles, Jonsson Comprehensive Cancer Center, will write a formal report on the meeting.

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"RFA Game" Defeats Purpose Of OAM, Advisor Complains

In a letter to Sen. Tom Harkin, a member of the NIH advisory council on alternative medicine accused the Institutes of steering funds to academic institutions, objected to playing the "game of RFAs for grants to universities" and said the group will be no more effective than "an advisory committee of eunuchs in the brothel."

The letter is noteworthy for two reasons:

1. Its author, Gar Hildenbrand, executive director of San Diego-based Gerson Research Organization, appears to have come to Bethesda expecting that the advisory body on which he was placed would have the sweeping powers to review and approve grants and select topics for investigation.

2. Hildenbrand was placed on the advisory council guiding the NIH Office of Alternative Medicine as a result of an intercession by Harkin, an Iowa Democrat who heads the Appropriations Committee's Subcommittee on Labor, HHS, Education and Related Agencies.

Atypical Scientific Advisors

As the advisory council begins to function, NIH finds itself having to reckon with Hildenbrand and other alternative medicine advocates whose expectations, perceptions and schooling make them atypical members of scientific advisory bodies. Hildenbrand's letter, dated Sept. 6, is the outcome of the volatile initial meeting of the OAM advisory council Aug. 31 through Sept. 1.

How this drama will play out is anyone's guess, but many officials express reactions that range from fear to dismay. Consider the first meeting of the alternative medicine panel:

One altercation ensued when former House member (and Harkin's friend) Berkley Bedell asked to go into a closed session in order to take a vote on the candidate for the directorship of NIH Office of Alternative Medicine.

The vacancy was created by the current director Joseph Jacobs, who quit, calling the job one of the more "non-holistic" in Washington (**The Cancer Letter**, July 15).

Bedell was told that under the Federal Advisory Committee Act it would be illegal for the council to go into a closed session, several sources who were present at the meeting said to **The Cancer Letter**.

"Scales Are Tipped"

In his letter to Harkin, Hildenbrand, describes the incident with gusto:

"I guess I saw the light when Joe Jacob's [sic.] *secretary* gave Berkley Bedell a dressing down the likes of which I haven't seen since the day you lit into [former NIH Deputy Director] Dr. Jay Moskowitz [at a Senate hearing last year].

"*She* was telling *Berkley* what he could and could not say," Hildenbrand wrote. "This was in front of NIH staff , the OAM advisory council, OAM staff, the media, and visitors. It didn't take someone with the wisdom of Solomon... to see that the scales were tipped the wrong way."

Conflict Over RFA

The group on which Hildenbrand serves is a "program advisory council" advising the Office of Alternative Medicine, which, being a part of the Office of the NIH Director, does not have a grant-making authority, NIH officials said.

Another conflict flared up over an RFA to create up to four "exploratory centers" to study multidiciplinary approaches in the theme areas including cancer and pain management.

Hildenbrand, among others, characterized the project as a way to channel alternative medicine dollars toward academic medicine.

The RFA, which was to distribute $1.8 million in grants for the first year, was issued during the year-and-a-half period when OAM did not have a standing advisory board.

Writes Hildenbrand:

"I learned, to my great dismay, that NIH Deputy Director Ruth Kirschstein had stiff-armed her way through with a scheme to divert the lion's share (estimates range from $7-10 million) of OAM's discretionary budget to the universities.

"Senator, the universities haven't been a bit more on the ball about alternative medicine than NIH itself."

President Of Gerson Organization

Hildenbrand is president and executive director of Gerson Research Organization, which is identified on the letterhead as "a non-profit public benefit corporation for research and service to patients and professionals."

The Gerson therapy for cancer, which includes a dietary intervention, vitamins, dietary supplements

and enemas with decaffeinated coffee, is available in Tijuana, Mexico.

Sources said that the list of candidates for the advisory panel originally prepared by the NIH Office of Alternative Medicine did not include Hildenbrand as a member. He was placed on the council as a result of an intervention by Harkin's office, NIH sources said.

"Dr. Kirschstein worked very hard with that committee to help them have a productive future in advising the OAM," Anne Thomas, NIH associate director for communications, said to **The Cancer Letter**. "We hope the group will work effectively within its charter."

"The Senator has had concerns in the past about the way the office has been administered," said Jodie Silverman, Harkin's press secretary. "He has not heard about this concern or looked into it."

Letter "Reflects My Concerns"

In an interview with **The Cancer Letter**, Hildenbrand said he stood by the points he made in the letter.

"The letter accurately reflects my concerns about what I thought I heard said at the meeting," he said. "The concerns are valid, and should be dealt with soon, to get them out of the way."

Hildenbrand declined to say whether he had received any response from Harkin or his staff. "I prefer not to comment on that," he said. "They've got to speak for themselves."

Hildenbrand said he did not intend the letter for wide circulation. "I am comfortable in what I wrote as an inside communication," he said. "If were given a chance to put out a sound bite before the media, I might not have used that language exactly."

The excerpted text of Hildenbrand's letter follows:

"Senator, NIH has done it again!

"You asked them to assemble a group of advisors to tell them what to study, tell them where the hope might have lain while they pursued other goals. Their interpretation of that request was to reduce the advisory "council" to a "committee"—simple as that—coach becomes pumpkin.

"Senator, why is it that NIH has the right to take a directive from you, spin-doctor it 180 degrees and implement it without ever having to ask you, "Did we get it right?" Instead, their tacit message to you is, "Give us money; we'll do our own shopping..."

"Because they read 'council' as 'committee,' NIH is now free to excommunicate its advisors from the big bucks university programs, That means, in short, no chance to review grants, and no oversight of research into alternatives...

"NIH says they reviewed the law. Odd thing is that an OAM staffer (who is quacking in his boots for fear that his name might get back to Dr. Kirschstein) tells me that NIH General Counsel's *original* opinion was that the 'council' could review, act, approve, and sign off on grants and research procedures, select alternatives for study, etc. Then, someone 'up above' intervened, took over the council's advisory 'charter,' and all of a sudden, the council became a 'committee.' Committees have no power to act. NIH has to 'listen' to committees, but they don't have to take their advice.

"Senator, the only place OAM's long-awaited advisory council can function is in the realm of field investigations. I might add that the phrase "field investigations" is regarded by NIH as an expletive suitable for deletion. The *very second* we get into Dr. Kirschstein's game of RFAs for grants to universities, the *advisors are officially excommunicated.* Period...

"May I recommend, Senator, that you request of Senate's General Counsel a review of the statutes and court decisions which NIH insists are responsible for devaluation of the voice of the community? They say there's a law which obliges them to interpret your requests and the reauthorization language as having created and advisory committee of eunuchs in the brothel..."

Capitol Notes

House, Senate Agree On NCI FY95 Appropriations: $1.91 Bil.

Appropriations for NCI remained unchanged at $1,919,419,000, as House and Senate conferees met to reconcile the differences between the two appropriations bills last week.

The final FY 1995 appropriations level is $48.5 million below the President's budget proposal of $1,967,709,000.

In fiscal 1994, NCI was appropriated $1,863,514,000. The conferees added report language to "strongly encourage" the Institute to expand

research in dietylstilbestol (DES).

The conferees gave NIH $11,334,098,000. The final figure is about $900,000 above the level recommended by the Senate and about $12.1 million above the level recommended by the House. However, it is $137.8 million below the President's budget request.

In fiscal 1994, NIH received $10,937,653,000.

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There will be no health care reform legislation reported by the 103rd Congress, the Democratic leadership announced earlier this week.

Senate Majority Leader George Mitchell (D-ME) ascribed the demise of the proposal to opposition by Republicans and a campaign by the insurance industry.

President Clinton and other Democrats vowed to reintroduce the health reform legislation in 1995.

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In a letter to FDA Commissioner David Kessler, Sen. Arlen Specter (R-PA) questioned FDA's decision to preclude Bristol-Myers Squibb Co. from distributing reprints of chapters from "Cancer: Principles & Practice in Oncology," edited by Vincent DeVita, Samuel Hellman and Steven Rosenberg.

Two years ago, FDA prevented Bristol from distributing the reprints, prepared by J.B. Lippincott & Co., at the American Society for Clinical Oncology annual meeting (**The Cancer Letter,** June 19, 1992).

In a letter last month Specter requested FDA to provide a legal justification for its actions.

"One of my constituents, J.B. Lippincott & Co. of Philadelphia, has brought to my attention several actions taken by FDA that appear to reflect a policy to prohibit or restrict the distribution by pharmaceutical companies of well recognized, independently prepared medical textbooks and treatises that are routinely used in medical schools and by physicians in clinical settings," Specter wrote.

"I am concerned that by taking steps to restrict textbook distribution, FDA may be treading on the rights of health care providers to receive information and of publishers and pharmaceutical companies to disseminate information.

"I am not aware of any other government agency that restricts distribution of publications that were not prepared for promotional purposes. I am also concerned that these actions may have an adverse impact on the practice of good medicine by denying health care providers access to the latest information."

In Brief

Three Win Albert Lasker Medical Research Awards

ALBERT LASKER MEDICAL Research Awards, given by the Albert and Mary Lasker Foundation, were announced this week. **STANLEY PRUSINER,** professor of neurology and biochemistry at the Univ. of California, San Francisco, who proved the existence of prions, disease-causing proteins that are neither bacteria nor viruses nor comprised of any genetic material, received the Albert Lasker Basic Medical Research Award. **JOHN CLEMENTS,** professor of pediatrics at the Univ. of California, San Francisco, who discovered the role of lung surfactant in the normal lung function of premature infants and developed a synthetic version of it, is the winner of the Albert Lasker Clinical Medical Research Award. **MACLYN McCARTY,** professor emeritus at the Rockefeller Univ., whose historic discovery that DNA is the chemical substance of heredity, is the winner of the Albert Lasker Special Public Health Award. The Public Health Award recognizes the golden anniversary of McCarty's accomplishment. The award has been given only four times in the awards program's 49-year history. The awards were presented in New York by Jordan Gutterman, director of the awards program. HHS Secretary Donna Shalala delivered the keynote address. . . . **TWENTY-NINE** universities and cancer centers received about $5 million in research awards from the CaP CURE, the Association for the Cure of Cancer of the Prostate, last week. The nonprofit organization was founded by Michael Milken last year. The association sponsored free prostate and breast cancer screening on Capitol Hill last week, and held an awards dinner. . . . **DAVID GOLDENBERG,** president of the Garden State Cancer Center in Newark, NJ, and **JEAN-PIERRE MACH** of Lausanne, Switzerland, shared the 1994 Abbott Award, given annually to a member of the International Society for Oncodevelopmental Biology and Medicine who has performed meritorious research and provided distinguished service to the society. The cancer center is completing the acquisition of the Essex County Geriatric Center under a $10.5 million grant from the US Dept. of Energy, in order to expand the center's clinical trials and laboratory research programs. . . . **NATIONAL INSTITUTE** of Allergy and Infectious

Diseases has awarded a grant to the consortium of Fred Hutchinson Cancer Research Center and Targeted Genetics Corp. to support the development of innovative therapies to fight HIV infection. The award was granted to six research teams under a new program launched by NIAID called the Strategic Program for Innovative Research on AIDS Treatment (SPIRAT). Targeted Genetics is collaborating with Philip Greenberg, Stanley Riddell, and Mark Gilbert at the FHCRC on two projects covered by the SPIRAT. . . .

MORE AGGRESSIVE measures are needed to couteract the social forces that continue to induce a quarter of the nation's young people to use tobacco products, a committee of the Institute of Medicine has concluded. The new report recommends a youth-centered tobacco control strategy that leans strongly toward legislative and regulatory action. The committee urged Congress to enact legislation allowing the Public Health Service to regulate the packaging and makeup of all tobacco products and to prescribe ceilings on tar and nicotine content. A large increase in the federal excise tax on tobacco products and tougher regulation of tobacco advertising, sales and promotion also are among the report's recommendations. Several research needs were identified by the committee, including smoking trends and differences among ethnic groups, responses by children to tobacco advertising, and the effectiveness of different public policies. The report, "Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths," is available from the National Academy Press, 2101 Constitution Ave. NW, Washington, DC 20418, Tel. 202/334-3313 or 800/624-6242. Cost of the report is $24.95 plus shipping of $4 for the first copy and $.50 for each additional copy.

NIH Human Embryo Panel Defines Acceptable Research

The NIH Human Embryo Research Panel said this week that federal funding for research involving human embryos is "acceptable public policy" provided the research is subject to strict guidelines.

After eight months of deliberations, the panel recommended that research proposals be subject to review by an ad hoc NIH research panel in addition to existing levels of review. The panel's report described in detail situations in which it believes that human embryo research is appropriate and when it is not.

The panel was chaired by Steven Miller, president emeritus of the Johns Hopkins Univ.

Among research the panel deemed unacceptable for federal funding were: cloning of human preimplantation embryos by separating blastomeres or dividing blastocysts, followed by transfer in utero; studies designed to transplant embryonic or adult nuclei into an enucleated egg, including nuclear cloning, in order to duplicate a genome or to increase the number of embryos with the same genotype, with transfer; research beyond the onset of closure of the neural tube; research involving the fertilization of fetal oocytes with transfer; preimplantation genetic diagnosis for sex selection except for sex-linked genetic diseases; development of human-nonhuman and human-human chimeras with or without transfer.

Fewer Young Scientists Win NIH Grants, NRC Study Finds

During the past decade, the number of life scientists younger than 37 applying for research grants from NIH has plummeted more than 50 percent, according to a report from a committee of the National Research Council.

About 700 fewer young scientists are conducting NIH-supported research today than were during the mid-1980s. The reasons for this decline are not yet known—it was recognized only recently during the committee's analysis of new data about NIH grants for fiscal year 1993. The pattern is so striking that the Research Council is developing plans for a new study to determine its cause.

Meanwhile, many scientists are concerned that overall cuts in government funding have had a disproportionately negative effect on people beginning their careers as independent researchers. But the committee found that biological and biomedical researchers in all age groups have more difficulty today obtaining government research funds than in the early and mid-1980s. During that period, researchers younger than 37 held a slight advantage over scientists in other age groups. Now they are no more likely to receive federal funds than are their older peers.

Copies of "The Funding of Young Investigators in the Biological and Biomedical Sciences" are available from the National Academy Press, 2101 Constitution Ave. NW, Washington, DC 20418, for $24 (prepaid) plus shipping charges of $4 for the first copy and $.50 for each additional copy; Tel. 202/334-3313 or 1-800-624-6242.

NIH Study Sections To Use New Triage Review System

All NIH standing study sections, beginning with the review of investigator-initiated research project grant applications (R01s and R29s) submitted for the Oct. 1 receipt date, will use the new method of triage, the Div. of Research Grants announced last week.

In a notice in the Sept. 23 "NIH Guide to Grants and Contracts," the DRG said reviewers will designate about half of the applications submitted as "noncompetitive" for support. The designation will require unanimous agreement of the study section.

"For this purpose, 'noncompetitive' means that the application is judged to be in the lower half, qualitatively, of research project grant applications normally reviewed by that study section," according to the notice.

Applications deemed "noncompetitive" will not receive full discussion at the study section meeting, will not receive a priority score, and will not be taken to second level of review by the national advisory councils/boards, the notice said.

The "noncompetitive" applications will be given a summary statement consisting of the usual administrative information and the reviewers' critiques.

"The summary statement for an application that receives full discussion and a score will include, in addition to the reviewers' critiques and the administrative information, a "Resume and Summary of Discussion," which synopsizes the study section's discussion of the application," the notice said. "Subsequent to the study section meeting, all applicants will receive the customary snap-out mailer to advise them of the outcome of the initial review."

NIH Grants Administration Seminar

A regional seminar covering topics related to NIH program funding and grants administration has been scheduled for Nov. 17-18, in Albuquerque, NM, hosted by the Univ. of New Mexico.

Staff from small and minority colleges, for-profit research organizations, hospitals, universities, and medical centers are encouraged to attend. Discussions of current issues that affect NIH funding and grants administration will be featured to give seminar participants a comprehensive view of NIH-sponsored research.

The faculty will include Geoffrey Grant, Joellen Harper, and Sue Ohata from the Office of Policy for Extramural Research Administration; Wayne Berry, Div. of Financial Management; Faye Calhoun, Div. of Research Grants; Joseph Ellis, NIA; Marvin Kalt, NCI; Mary Kirker, NIAID; Yvonne Maddox, NIGMS; and Carol Tippery, NIGMS.

Advance registration is required. To receive the draft program and registration materials, call 505/277-3942, or send a fax that provides your name, institution, address, telephone number, and anticipated number of registrants to 505/277-8604.

RFAs Available

RFA AI-94-027

Title: **Enhancement Awards For Underrepresented Minority Researchers In HIV/AIDS**

Letter of Intent Receipt Date: Dec. 23

Application Receipt Date: Feb. 21

The goal of this support is to enable underrepresented minority investigators to establish clinical or basic AIDS research programs.

To move towards this goal, the National Institute of Allergy and Infectious Disease (NIAID) encourages applications from underrepresented minority investigators for both basic and clinical investigations in AIDS and AIDS-related research. Several features have been employed to achieve these goals. These include the fostering of specific collaborations between more established investigators and the Principal Investigator to enhance refinement and implementation of each proposed project to maximize the chances for success.

Support will also be provided for laboratory staff of the qualified PI, including postdoctoral scientists who will augment the research program established by the grantee.

Applications in all basic and clinical areas of HIV/AIDS research are encouraged. NIAID anticipates awarding four to six R01 awards, for a total (direct and indirect) cost of approximately $1.2 million for the initial year of funding.

The RFA, which describes the research objectives, application procedures, review considerations, and award criteria for this solicitation, may be obtained electronically through the NIH Grant Line (data line 301/402-2221) and the NIH GOPHER (Internet) and by mail and email from the program contact listed below.

Inquiries: Janet Young, Div. of AIDS, NIAID, Solar Bldg. Rm 2C36, Bethesda, MD 20892, Tel: 301/402-0755, FAX: 301/480-5703, Internet: enhance@nih.gov.

RFA HL-95-002

Title: **Mechanisms Of Post Bone Marrow Transplantation Lung Injury**

Letter of Intent Receipt Date: Dec. 1

Application Receipt Date: Jan. 19

The National Heart, Lung, and Blood Institute invites research grant applications to support research on immunological, cellular, and molecular mechanisms of post bone marrow transplantation lung injury. The primary objectives of this special grant program are to determine the etiology and to understand the cellular and molecular mechanisms involved in the pathogenesis of idiopathic pneumonia syndrome (IPS) that frequently follows bone marrow transplantation. Applications may be submitted by domestic organizations.

This program will be awarded using an incremental funding method that is being tested by NIH. Funds must be requested in increments of $50,000 each (direct costs) and a maximum of four increments ($200,000 direct costs) per year may be requested. Up to four years of support may be requested for these R01s. Only limited budget information will be required and any budget adjustments made by the Initial Review Group will be in increments of $50,000. The estimated funds (total costs) available for the first year of support for the entire program is $1.5 million. It is anticipated that no more than eight awards will be issued.

Inquiries: Hannah Peavy, Div. of Lung Diseases, NHLBI, Westwood Bldg. Rm 6A09, Bethesda, MD 20892, Tel: 301/594-7425, FAX: 301/594-7487.

RFA AI-94-029

Title: **Pediatric AIDS: Factors In Transmission And Pathogenesis**

Letter of Intent Receipt Date: Nov. 15

Application Receipt Date: Feb. 16

The Div. of AIDS of the National Institute of Allergy and Infectious Diseases invites applications for research designed to study transmission and pathogenesis of HIV-1 in infants and children. Applications are sought for laboratory studies that elucidate: (1) the timing and mechanism of transmission of HIV from mother to infant or (2) factors that determine whether infected children become long-term asymptomatic survivors or suffer from rapidly progressive disease. NIAID seeks applications for research studies that utilize advances in virology, immunology, and genetics to address these questions. Of special interest are those basic research studies that hold promise for development of clinical strategies to prevent mother-to-infant transmission of HIV-1 or to treat perinatally infected children to prolong and improve the quality of their lives. For applications proposing use of clinical specimens, documented access to an adequate number of samples to address the study hypotheses will be required.

Research grant applications may be submitted by domestic and foreign organizations. The mechanisms of support will be the individual research project grant (R01) and the FIRST (R29) award (foreign institutions not eligible for R29s). Multidisciplinary approaches that involve collaborative efforts among investigators in the fields of basic immunology, molecular biology, genetics, virology, and infectious disease are strongly encouraged. The total project period may not exceed five years.

The estimated total funds (direct and indirect costs) available for the first year of support will be $2,000,000. In FY 1995, NIAID plans to fund 12 R01s/R29s.

Inquiries: Bonnie Mathieson or Patricia Fast, Div. of AIDS, NIAID, 6003 Executive Blvd. Solar Bldg. Rm 2B06, Bethesda, MD 20892, Tel: 301/496-8200, FAX: 301/402-1506 or 301/480-5703.

PA-94-095

Title: **Drug Discovery For Opportunistic Infections Associated With AIDS**

The purpose of this Program Announcement is to solicit new research grant applications aimed at novel approaches to discovery and preclinical development of therapeutic agents active against opportunistic infections in people with AIDS. The research scope will focus on basic and applied studies necessary to propel advances in improved therapies. The intent of this PA is to invite applications for support of investigator-initiated research grants and the Interactive Research Project Grants (IRPG) mechanisms. No clinical trials will be supported.

Applications may be submitted by foreign and domestic organizations. Applications may be submitted from one institution or may include arrangements with several institutions, if appropriate. Foreign institutions are not eligible for R29 awards.

Support will be by R01, FIRST (R29) award, or IRPG. If an IRPG is proposed, it must consist of a minimum of two independent applications. Collaborative arrangements involving more than one institution are especially encouraged, including participation of the pharmaceutical industry where appropriate.

The objective of this PA is to stimulate drug discovery through original and innovative research focused on key metabolic and pathophysiologic features, which will lead to the development of safe, well-tolerated, and effective new therapies for treatment and prophylaxis of AIDS-associated OIs. Applications based on sound scientific rationale encompassing in vitro culture systems and/or animal models to conduct the necessary preclinical studies are encouraged.

The research scope encourages applications for studies on the following pathogens: human cytomegalovirus (CMV), Mycobacterium tuberculosis, Mycobacterium avium, Pneumocystis carinii, Toxoplasma gondii, and Cryptococcus neoformans. Innovative research focusing on other particularly prevalent or problematic infections associated with AIDS is also encouraged.

Inquiries: Barbara Laughon, Div. of AIDS, NIAID, Solar Bldg Rm 2C26, 6003 Executive Blvd, MSC 7620, Bethesda, MD 20892-7620, Tel: 301/402-2304, FAX: 301/402-3211, Email: barbara_laughon@nih.gov.