

do the investigators have the potential of impacting the medical processes within their communities, but also, the ability to engage in, as well as promote the development of research programs that reflect an understanding of the variety of issues and problems associated with disparities in health status. This emphasis is consistent with the statute and the goals of both the NCMHD and the NIH to develop a diversified biomedical and behavioral research workforce and to reduce health disparities. Being a member of a health disparities population, however, is not a prerequisite for participation in the HDR-LRP. Any qualified health professional may apply for the program, provided the individual is conducting minority health or other health disparities research and meets all other eligibility requirements.

Participant's Obligation

In exchange for the NCMHD repaying the participants' educational loans, participants must agree to: (1) Engage in minority health or other health disparities research for a minimum of 2 years; (2) make payments to lenders on their own behalf for periods of Leave Without Pay (LWOP); (3) pay monetary damages as required for breach of contract; and (4) satisfy other terms and conditions of the contract and application procedures.

Program's Obligations

Under the HDR-LRP, the NCMHD will make loan repayments to the designated lenders following the completion of each full quarter (3 months) of service by the participants and upon receipt of requested documentation from the participants and their supervisors/mentors. The total repayment amount shall not exceed \$35,000 per year for each year of obligated service.

Participants will not automatically qualify for the maximum amount of loan repayment. The amount the NCMHD will consider for repayment during the initial two-year contract shall be calculated as follows: one-fourth the repayable debt per year, up to a maximum of \$35,000 per year. (Example: A participant with a base salary of \$40,000 per year and an outstanding eligible educational loan debt of \$100,000, would have a debt threshold of \$8,000 and the repayable debt would be \$96,000. Of the \$96,000 repayable debt amount, the NCMHD would repay \$24,000 a year in loan repayments—a total of \$48,000 would be repaid over the two-year contract period.) Following the conclusion of the initial two-year contract, participants

may apply for renewal contracts to satisfy any remaining repayable debt. Requests for renewal contracts are considered for approval on a competitive year-to-year basis. Funding of renewal contracts is contingent upon appropriation and/or allocation of funds from the U.S. Congress, the NIH and/or NCMHD.

Payment of Loans

Because the first payment to the lenders on behalf of the participants will not commence until the end of the first full quarter of obligated service, participants should continue to make monthly loan payments until they have been informed that payments have been forwarded to their lenders. This measure enables the participants to maintain their loans in a current payment status.

The HDR-LRP will repay loans in the following order unless the Director of NCMHD, determines that significant savings would result from repaying loans in a different priority order:

- (1) Loans issued or guaranteed by the U.S. Department of Health and Human Services;
- (2) Loans issued or guaranteed by the U.S. Department of Education;
- (3) Loans issued or guaranteed by a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or possession of the United States;
- (4) Loans issued or guaranteed by an Academic Institution; and
- (5) Other qualifying loans.

If the participant has multiple loans in a given category, loans will be prioritized according to the interest rate (highest to the lowest).

Financial obligations that do not qualify for repayment under the HDR-LRP include:

- (1) Loans not obtained from a government entity, academic institution, or commercial or other chartered lending institution (such as loans obtained from friends, relatives, or other individuals);
- (2) Loans for which contemporaneous documentation is not available;
- (3) Loans or portions of loans obtained for educational or living expenses which exceed a reasonable level as determined by the HDR-LRP upon review of the standard school budget or additional contemporaneous documentation for the year in which the loan was made;
- (4) Delinquent loans, loans in default, loans not current in their payment schedule, loans already repaid or those for which promissory notes have been signed after the contract has been executed by the Director of NCMHD;

(5) Parent Loan for Undergraduate Students (PLUS);

(6) Loans consolidated with another individual, including a spouse;

(7) Equity loans that include educational loans as part of their balance or any other types of equity loans; and

(8) Loans, financial debts or service obligations that convert to a loan or debt for failure to satisfy the service obligation. Programs that incur service obligations include but are not limited to the following:

- Physicians Shortage Area Scholarship Programs;
- National Research Service Award Program;
- National Health Service Corps Scholarship Program;
- Armed Forces (Army, Navy or Air Force) Health Professions Scholarship Program; and
- Indian Health Service Scholarship Program.

During lapses in loan repayments, due either to administrative complications or a break in service, HDR-LRP participants are wholly responsible for making payments or other arrangements to keep loans in a current payment status and to avoid incurring any additional increase in either principal or interest. Penalties assessed participants as a result of administrative complications may be considered for reimbursement.

Additional Program Information

This program is not subject to the provision of Executive Order 12372, Intergovernmental Review of Federal Programs. Under the requirements of the Paperwork Reduction Act of 1995, OMB has approved the application forms for use by the HDR-LRP under OMB Approval No. 0925-0361 (expires December 31, 2004).

The *Catalog of Federal Domestic Assistance* number for the HDR-LRP is 93.307.

Dated: July 19, 2002.

Elias A. Zerhouni,
Director, National Institutes of Health.
[FR Doc. 02-18941 Filed 7-25-02; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Extramural Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) invites applications for the Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR-LRP or Program) for fiscal year 2002. Pursuant to authority granted by Public Law 106-554, The Consolidated Appropriations Act of 2001, that amended section 487E of the Public Health Service (PHS) Act (42 U.S.C. 288-5), as added by the National Institutes of Health Revitalization Act of 1993 (Public Law 103-43), the Secretary of Health and Human Services (Secretary), acting through the Director of NIH, has established a loan repayment program that offers the repayment of educational loan debt to qualified health professionals from disadvantaged backgrounds, that have substantial debt relative to income, and agree to conduct clinical research. The Director of NIH may enter into contracts with qualified health professionals from disadvantaged backgrounds that agree to engage in clinical research for a minimum of 2 years in exchange for loan repayments toward their outstanding educational loan debt, up to a maximum of \$35,000 per year.

DATES: Interested persons may request information about the ECR-LRP beginning on July 26, 2002, and August 23, 2002, at 5 p.m. (eastern time) is the closing date and time for the application process.

ADDRESSES: Information regarding the requirements and application procedures for the ECR-LRP may be obtained by calling or writing: National Center on Minority Health and Health Disparities, 6707 Democracy Blvd., Suite 800, MSC 5465, Bethesda, MD 20892-5465, Attention: Kenya McRae, non-toll-free number: (301) 402-1366, e-mail: mcraek@od.nih.gov, Web site: <http://www.ncmhd.nih.gov>; or the Office of Loan Repayment Program, National Institutes of Health, toll-free-number: (866) 849-4047, e-mail: lrp@nih.gov, Web site: <http://www.lrp.nih.gov>.

SUPPLEMENTARY INFORMATION:

Definitions

(1) "Clinical research" is defined as patient-oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or

epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.

(2) "Debt threshold" is the minimum amount of qualified educational loan debt an applicant must have in order to be eligible for Program benefits. An applicant must have qualified educational loan debt equal to at least 20% of the applicant's institutional base salary or compensation at the time of execution of the LRP contract.

(3) An "individual from a disadvantaged background" is defined as one who: (a) Comes from an environment that inhibited the individual from obtaining the knowledge, skill and ability required to enroll in and graduate from a health professions school; or (b) comes from a family with an annual income below a level based on low-income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for the changes in the Consumer Price Index, and adjusted by the Secretary of the U.S. Department of Health and Human Services (Secretary) for use in all health professions programs. The Secretary periodically publishes these income levels in the **Federal Register**. An applicant must certify his/her disadvantaged status under the above definition by submitting: (a) A written statement from the individual's former health professions school(s) that indicates that he/she qualified for Federal disadvantaged assistance during attendance; or (b) a personal statement explaining the applicability of the above definition to his/her circumstances (such statement should indicate the city, state and county where the applicant received the majority of his/her secondary education); or (c) documentation that he/she has received any of the following financial aid: Health Professions Student Loans (HPSL); Loans for Disadvantaged Student Program; Scholarship for Individuals with Exceptional Financial Need; or other specific loans or scholarships designated for disadvantaged students. Current financial need alone is NOT sufficient to classify an individual as being from a disadvantaged background.

(4) "Qualified educational loan debt" is defined as educational loan debt incurred by health professionals for their undergraduate, graduate and/or health professional school educational expenses incurred at accredited institutions. It consists of the principal, interest, and related expenses of qualified Government and commercial

loans obtained by the applicant for: (a) Tuition expenses; (b) other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and (c) the cost of room and board, and other reasonable living expenses as determined by the Secretary or his designee.

(5) "Repayable debt" means the difference between the applicant's qualified educational loan debt and 50% of the applicant's debt threshold.

Background

The Consolidated Appropriations Act of 2001 (Public Law 106-554) was enacted on December 21, 2000, amending 487E of the Public Health Service (PHS) Act to authorize the Secretary of the Department of Health and Human Services (Secretary), through the Director of the National Institutes of Health (NIH), to enter into contracts with qualified health professionals from disadvantaged backgrounds. These health professionals are required to engage in clinical research in consideration of the Federal Government repaying a portion of the principal and interest of their educational loans, up to a maximum of \$35,000 per year, for each year of service. The program is known as the Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR-LRP). Selected applicants become participants of the ECR-LRP only upon the execution of a contract by the Secretary or his designee.

Eligibility Requirements

Specific eligibility criteria with regard to participation in the ECR-LRP include the following:

(1) Applicants must be a United States citizen, national, or permanent resident.

(2) Applicants must have a M.D., Ph.D., Pharm.D., D.O., D.D.S., D.M.D., D.P.M., Sc.D., or equivalent doctorate degree from an accredited institution.

(3) Applicants must come from a disadvantaged background.

(4) Applicants must have qualifying outstanding educational loan debt equal to or in excess of 20 percent of their institutional base salary or compensation. (Example: An applicant with a base salary of \$40,000 per year must have a minimum outstanding educational loan debt of \$8,000).

(5) Applicants must not be Federal employees.

(6) Applicants must have a research sponsor or mentor with experience in the area of proposed research and may be enrolled in a training program or

appointed under a temporary or permanent employment mechanism for at least two years. (Postdoctoral fellows and physicians completing their residencies are eligible to apply provided they meet all other eligibility requirements).

(7) Applicants must agree to engage in qualified clinical research for the entire period of their contract.

(8) Individuals with existing service obligations to Federal, State, or other entities may not apply for the ECR-LRP, unless and until the existing service obligation is discharged or deferred for the length of program participation.

(9) Individuals that have a Federal judgment lien against their property arising from a Federal debt from receiving Federal funds may not apply for the ECR-LRP until the judgment has been paid in full or otherwise satisfied.

(10) Individuals will not be excluded from consideration under the ECR-LRP on the basis of age, race, culture, religion, gender, sexual orientation, disability or other non-merit factors.

Application Procedures and Selection Process

Individuals should submit their completed on-line application package to the Director of the Office of Loan Repayment (OLR) who will forward it to the NCMHD, 6707 Democracy Boulevard, Suite 800, MSC 5465, Bethesda, MD 20892-5465. The NCMHD and OLR have provided the current deadlines, sources for assistance, and additional details regarding application procedures in an Applicant Information Bulletin located at the NIH LRP home page at <http://www.lrp.nih.gov>.

The NCMHD will forward all qualified applications to the NCMHD Loan Repayment Review Panel (Panel), chaired by the Deputy Director, NCMHD, for review. The Panel will review and rank the applications based on criteria deemed appropriate, such as the personal statement, recommendations, training plan, research statement, institutional statement and research environment.

Only applications receiving approval from the Panel and having contracts executed by the Director of NCMHD will receive funding, subject to the receipt of an appropriation and/or allocation of funds from the U.S. Congress, the NIH and/or NCMHD.

Participant's Obligation

In exchange for the NCMHD repaying the participants' educational loans, participants must agree to: (1) Engage in qualified clinical research for a minimum of 2 years; (2) make payments

to lenders on their own behalf for periods of Leave Without Pay (LWOP); (3) pay monetary damages as required for breach of contract; and (4) satisfy other terms and conditions of the contract and application procedures.

Program's Obligations

Under the ECR-LRP, the NCMHD will make loan repayments to the designated lender following the completion of each full quarter (3 months) of service by the participant and upon the receipt of requested documentation from the participants and their supervisors/mentors. The total repayment amount shall not exceed \$35,000 per year for each year of obligated service.

Participants will not automatically qualify for the maximum amount of loan repayment. The amount the NCMHD will consider for repayment during the initial two-year contract shall be calculated as follows: one-fourth the repayable debt per year, up to a maximum of \$35,000 per year. (*Example:* A participant with a base salary of \$40,000 per year and an outstanding eligible educational loan debt of \$100,000, would have a debt threshold of \$8,000 and the repayable debt would be \$96,000. Of the \$96,000 repayable debt amount, the NCMHD would repay \$24,000 a year in loan repayments—a total of \$48,000 would be repaid over the two-year contract period.) At the end of the initial two-year contract, participants may apply for renewal contracts to satisfy any remaining repayable debt. Requests for renewal contracts are considered for approval on a competitive year-to-year basis. Funding of renewal contracts is contingent upon appropriation and/or allocation of funds from the U.S. Congress, the NIH and/or NCMHD.

Payment of Loans

Because the first payment to the lenders on behalf of the participants will not commence until the end of the first full quarter of obligated service, participants should continue to make monthly loan payments until they have been informed that payments have been forwarded to their lenders. This measure enables the participants to maintain their loans in a current payment status.

The ECR-LRP will repay loans in the following order unless the Secretary determines that significant savings would result from repaying loans in a different priority order:

- (1) Loans issued or guaranteed by the U.S. Department of Health and Human Services;
- (2) Loans issued or guaranteed by the U.S. Department of Education;

(3) Loans issued or guaranteed by a State, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or possession of the United States;

(4) Loans issued or guaranteed by an Academic Institution; and

(5) Other qualifying loans.

If the participant has multiple loans in a given category, loans will be prioritized according to the interest rate (highest to the lowest).

Financial obligations that do not qualify for repayment under the ECR-LRP include:

(1) Loans not obtained from a government entity, academic institution, or commercial or other chartered lending institution (such as loans obtained from friends, relatives, or other individuals);

(2) Loans for which contemporaneous documentation is not available;

(3) Loans or portions of loans obtained for educational or living expenses which exceed a reasonable level as determined by the ECR-LRP upon review of the standard school budget or additional contemporaneous documentation for the year in which the loan was made;

(4) Delinquent loans, loans in default, loans not current in their payment schedule, loans already repaid or those for which promissory notes have been signed after the contract has been executed by the Secretary;

(5) Parent Loan for Undergraduate Students (PLUS);

(6) Loans consolidated with another individual, including a spouse;

(7) Equity loans that include educational loans as part of their balance or any other types of equity loans; and

(8) Loans, financial debts, or service obligations that convert to a loan or debt on failure to satisfy the service obligation. Programs with service obligations include, but are not limited to the following:

- Physicians Shortage Area Scholarship Programs;
- National Research Service Award Program;
- National Health Service Corps Scholarship Program;
- Armed Forces (Army, Navy or Air Force) Health Professions Scholarship Program; and
- Indian Health Service Scholarship Program.

During lapses in loan repayments, due either to administrative complications or a break in service, ECR-LRP participants are wholly responsible for making payments or other arrangements to keep loans in a current payment status and to avoid incurring any

additional increase in either principal or interest. Penalties assessed participants as a result of administrative complications may be considered for reimbursement.

Additional Program Information

This program is not subject to the provision of Executive Order 12372, Intergovernmental Review of Federal Programs. Under the requirements of the Paperwork Reduction Act of 1995, OMB has approved the application forms for use by the ECR-LRP under OMB Approval No. 0925-0361 (expires December 31, 2004).

The *Catalog of Federal Domestic Assistance* number for the ECR-LRP is 93.308.

Dated: July 19, 2002.

Elias A. Zerhouni,

Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Suppressing Unencoded MRI Signal Contribution in Multi-Phase Myocardial Tagging and Phase-Contrast Based Methods

Anthony H. Aletras (NHLBI)
DHHS Reference No. E-079-02/0

Licensing Contact: Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov.

The invention is a method for obtaining clear functional magnetic resonance (MR) cardiac images without significantly increasing signal acquisition time. During functional magnetic resonance imaging (MRI) the specimen magnetization is spatially encoded by application of one or more radio frequency pulses (RF) and gradient magnetic fields. This spatially encoded magnetization is then read out to produce images that can be used to assess specimen motion. During this process the contrast decreases from the beginning of the cardiac cycle as the magnetization decays or relaxes, making the images more difficult to process and interpret over time. This is currently solved by acquiring the images twice (with a modified signal excitation phase) to suppress unwanted unencoded MRI signal contributions; therefore improving the contrast. Unfortunately, this prolongs the acquisition by a factor of two. In the invention, an RF inversion pulse is used to suppress the undesirable unencoded MRI signal contributions, thereby improving the contrast. This RF frequency drives the undesired signal to an equilibrium around zero, while preserving the desired encoded signal. The application of the RF inversion pulse doubles the resolution of the image and does not increase acquisition time. It allows for immediate evaluation of myocardial contractility throughout the whole cardiac cycle without requiring user intervention during phase-based data processing. There is also the possibility that this method could be used in other areas of the body, including the spinal cord, and the invention may be applicable to the study of brain motion. This new method speeds up the quantification of datasets, suppresses undesired signal contributions, and doubles the resolution of the images without doubling acquisition time.

ELISA Assay of Serum Soluble CD22 to Assess Tumor Burden/Relapse in Subjects with Leukemia and Lymphoma

Robert Kreitman et al. (NCI)
DHHS Reference No. E-065-02/0 filed May 20, 2002
Licensing Contact: Richard Rodriguez; 301/496-7056 ext. 287; e-mail: rodrigur@od.nih.gov.

Disclosed are methods of using previously unknown soluble forms of CD22 (sCD22) present in the serum of subjects with B-cell leukemias and

lymphomas to assess tumor burden in the subjects. Also disclosed are methods of diagnosing or prognosing development or progression of a B-cell lymphoma or leukemia in a subject, including detecting sCD22 in a body fluid sample taken or derived from the subject, for instance serum. In some embodiments, soluble CD22 levels are quantified. By way of example, the B-cell lymphoma or leukemia can be hairy cell leukemia, chronic lymphocytic leukemia, or non-Hodgkin's lymphoma. Soluble CD22 in some embodiments is detected by a specific binding agent, and optionally, the specific binding agent can be detectably labeled.

Also disclosed are methods of selecting a B-cell lymphoma or leukemia therapy that include detecting an increase or decrease in sCD22 levels in a subject compared to a control, and, if such increase or decrease is identified, selecting a treatment to prevent or reduce B-cell lymphoma or leukemia or to delay the onset of B-cell lymphoma or leukemia.

Other embodiments are kits for measuring a soluble CD22 level, which kits include a specific binding molecule that selectively binds to the CD22, e.g. an antibody or antibody fragment that selectively binds CD22.

Further disclosed methods are methods for screening for a compound useful in treating, reducing, or preventing B-cell lymphomas or leukemias, or development or progression of B-cell lymphomas or leukemias, which methods include determining if application of a test compound lowers soluble CD22 levels in a subject, and selecting a compound that so lowers sCD22 levels.

Mutated Anti-CD22 Antibodies with Increased Affinity to CD22-Expressing Leukemia Cells

Ira Pastan et al. (NCI)
HHS Reference No. E-129-01/0 filed Sep 26, 2001
Licensing Contact: Richard Rodriguez; 301/496-7056 ext. 287; e-mail: rodrigur@od.nih.gov.

The present invention provides improved antibodies for binding to CD22-expressing cells (CD22 is expressed on B cells and B-cell malignancies), especially cancer cells that express CD22 on their exterior surface. In this regard, the invention provides anti-CD22 antibodies with a variable light (V_L) chain having the sequence of antibody RFB4 and a variable heavy (V_H) chain having the sequence of antibody RFB4, but in which residues 100, 100A and 100B of CDR3 of said V_H chain (as numbered by the Kabat and Wu numbering system)