Ms. Jessie K. Rasmussen,
Director, Iowa Department of Human Services, Hoover State Office Building, Des Moines, IA 50319–0114.

Dear Ms. Rasmussen: I am responding to your request for reconsideration of the decision to disapprove Iowa State Plan Amendment (SPA) 01–013. Iowa submitted Iowa SPA 01–013 on March 28, 2001. The issue is whether Iowa can limit Medicaid eligibility to members of the Balanced Budget Act of 1997 (BBA) buy-in group for the working disabled who have not attained age 65. This amendment seeks to limit Medicaid eligibility under the optional categorically needy group at section 1902 (a)(10)(A)(ii)(XIII) of the Social Security Act (the Act) to individuals under age 65. This group is more commonly known as the BBA buy-in group for the working disabled. Coverage of the group itself was approved via Iowa SPA 00–04. The SPA 01–013 seeks to add a limitation on the age of eligible individuals that was not included in SPA 00–04. For reasons explained below, the Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration, disapproved SPA 01–013.

Iowa requested approval of an age limit under the BBA group because State legislation authorizing coverage of the group limits eligibility to those under the age of 65. However, the Federal statute at section 1902(a)(10)(A)(ii)(XIII) of the Act does not provide for a limit on the age of individuals who can be eligible under this group, nor does that section include any authority for states to establish such a limit. Iowa argued that, while not stated explicitly, the intent of Congress in enacting the BBA group was that eligibility under the group be limited to individuals under age 65. The State bases its argument on a reference in subsection (XIII) to section 1905(q)(2)(B) of the Act as the authority for establishing the income limit for eligibility under the BBA group. Since eligibility in general under the group established at section 1905(q) of the Act (qualified severely impaired individuals) is limited to individuals under age 65, the State believes that age limit, through the subsection (XIII) reference to section 1905(q)(2)(B), also applies to the BBA group.

However, section 1902(a)(10)(A)(ii)(XIII) does not reference section 1905(q) in its entirety, but only subsection (2)(B), and then only in the specific context of the income limit set forth in that subsection. Accepting the argument that Congress intended, in referring to subsection (2)(B), that the age limit which applies to section 1905(q) in general should apply to the BBA group, logically leads to the conclusion that all of the other requirements of section 1905(q) would apply to the BBA group as well. However, this is clearly not the case because Congress established separate requirements for eligibility under the BBA group, adopting section 1905(q)(2)(B) only for purposes of establishing an income limit for that group.

The CMS believes its position to be supported by Congress' action to establish two additional groups under the Ticket to Work and Work Incentives Improvement Act of 1999 through which states can elect to cover working disabled individuals under Medicaid. The statutory provisions for both groups (sections 1902(a)(10)(A)(ii)(XV) and (XVI)) specifically limit eligibility to individuals who are at least 16 but not more than 64 years of age. Had Congress intended to limit eligibility under the BBA group to individuals under age 65, it could have amended section 1902(a)(10)(A)(ii)(XV) and (XVI) specifically limiting eligibility to individuals who are at least 16 but not more than 64 years of age. Had Congress intended to limit eligibility under the BBA group to individuals under age 65, it could have amended section 1902(a)(10)(A)(ii)(XIII) to provide such a limit.

The CMS had offered Iowa an alternative that would have enabled the State to avoid covering most individuals age 65 and over under the BBA group. The State could define the group as consisting only of individuals who meet the definition of disability under the Supplemental Security Income (SSI) program. By defining the group in this way, the State would not have to cover anyone age 65 or over who did not also meet the SSI definition of disability. However, Iowa was not able to take advantage of this alternative because of the specific language of the State's enabling legislation.

Therefore, after consulting with the Secretary as required by 42 CFR 430.15(c), CMS informed Iowa of its decision to disapprove this amendment.

I am scheduling a hearing on your request for reconsideration to be held on November 14, 2001, at 10:00 a.m. in Room 281, Richard Bolling Federal Building, 601 E. Twelfth Street, Kansas City, Missouri 64106. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR, Part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer. In order to facilitate any communication, which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing. The presiding officer may be reached at (410) 786–2055.

Sincerely,

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

Section 1116 of the Social Security Act (42 U.S.C. section 1316; 42 CFR section 430.18).

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: September 30, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–25227 Filed 10–3–01; 1:55 pm]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors—42 CFR Part 50, Subpart F

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed date collection projects, the Office of the Director (OD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors—42 CFR Part 50, Subpart F. *Type of Information Collection Request:* Revision of OMB No. 0925–0417, expiration date 03/31/2002. *Need and Use of Information Collections:* This is a request for OMB approval for the information collection and recordkeeping requirements contained in the final rule 42 CFR part 50 subpart F and Responsible Prospective Contractors: 45 CFR part 94. The purpose of the regulations is to promote objectivity in research by requiring institutions to establish standards which ensure that there is no reasonable expectation that the design, conduct, or reporting of research will be biased by a conflicting financial interest of an investigator. *Frequency of Response:* On occasion. *Affected Public:* Individuals or households; Business of other for-profit; Not-for-profit institutions; State, Local or Tribal Government. *Type of Respondents:* Any public or private entity or organization. The annual reporting burden is as follows: *Estimated Number of Respondents:* 42,800; *Estimated Number of Responses per Respondent:* 1.60; *Average Burden Hours per Response:* 3.40; and *Estimated Total Annual Burden hours Requested:* 232,000. The annualized costs to respondents is estimated at: $8,120,000. Operating costs and/or Maintenance Costs are $4,633.

Request for Comments

Written comments and/or suggestions from the public and affected agencies

are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Charles MacKay, Chief, Project Clearance Branch, Office of Extramural Research (OER), Office of Policy for Extramural Research Administration (OPERA), 6705 Rockledge Drive, Room 1198, Bethesda, MD 20892–7974 or call non-toll-free number (301) 435–0978 or E-mail your request including your address to: *MACKAYC@od.nih.gov.*

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before December 10, 2001.

Dated: September 26, 2001.

Carol Tippery,

Acting Director, OPERA, NIH.

[FR Doc. 01–25169 Filed 10–5–01; 8:45 am]

BILLING CODE 4140–01–M

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.

NEIBANK: Microarray for Human Eye Research

Dr. Graeme J. Wistow (NEI)
DHHS Reference No. E–107–01/0
Licensing Contact: Pradeep Ghosh; 301–496–7736 ext. 211; e-mail: *ghoshp@od.nih.gov*

Microarrays have wide applications in basic research and are used for the discovery of candidate genes as markers for disease and for therapeutic intervention. ''NEIBANK'', a new microarray research tool has been developed that allows researchers to compare expression levels of thousands of genes expressed in the eye. The technology comprises of a set of sequenced unamplified and normalized libraries derived from normal human eye tissues using a custom software, GRIST (Grouping and Identification of Sequence Tags). Using this technique, a non-redundant set of over 10,000 cDNA clones, potentially representing unique genes expressed in the human eye has been derived. This integrated technique of sequencing with bioinformatics led to the discovery of new genes and the novel splice forms of known genes. Thus, this technology can be used to examine processes of diseases, aging, normal and abnormal development in post-mortem or surgical eye samples and in cultured cell systems. Areas of particular interest for this array in eye research include, but are not limited to, retinal degeneration, age-related macular degeneration and cataract.

Intercellular Delivery of a Herpes Simplex Virus VP22 Fusion Protein From Cells Infected With Lentiviral Vectors

Dr. Zhennan Lai et al. (NINDS)
DHHS Reference No. E–295–00/0 filed 02 August 2001
Licensing Contact: Marlene Shinn; 301/496–7056 ext. 285; e-mail: *shinnm@od.nih.gov*

One of the current limitations to the use of gene therapy is the delivery of genes or proteins to a sufficient number of target cells in order to create a therapeutic response. It has recently been discovered that a series of virus-encoded and other regulatory proteins are able to cross biological membranes, leading to the discovery that the herpes simplex virus 1 tegument protein, VP22, could be used to direct the global delivery of therapeutic proteins intercellularly.

The NIH announces a new lentivirus double gene vector expressing recombinant VP22-fusion protein. The vector contains two separate transgenes driven by two independent promoters. A reporter gene replaced the nev region of the HIV–1 genome, and another selectable marker gene was inserted into the nef coding region. Both transgenes are simultaneously expressed in non-dividing cells such as neurons. When the gene for VP22-fusion protein is incorporated into the vector, the fusion gene product is delivered to the cytoplasm and nuclei of non-dividing mammalian cells in vitro and in vivo, and from transduced cells to neighboring (non-infected) cells.

Dated: September 28, 2001.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 01–25170 Filed 10–5–01; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel.

Date: November 1, 2001.

Time: 11:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.