Responses per Respondent: 1.0; Average *Burden Hours Per Response:* 0.225; and *Estimated Total Annual Burden Hours Requested:* 42. The annualized cost to respondents is estimated at $6,733. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

There are no capital operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Physicians	279	1.0	0.20	19
Participant proxies	276	1.0	0.25	23
Total	555	1.0	0.225	42

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) evaluate 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) enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Diane Bild, NIH, NHLBI, 6701 Rockledge Drive, MSC 7938, Bethesda, MD 20892–7934, or call non-toll-free number (301) 435–0457 or e-mail your request, including your address to: *BildD@nhlbi.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 -days of the date of this publication.

Dated: August 31, 2004.

Peter Savage,

Director, DECA, NHLBI.

[FR Doc. 04–20658 Filed 9–13–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Licensing Opportunity and/or Cooperative Research and Development Agreement (''CRADA'') Opportunity: Live Attenuated Respiratory Syncytial Virus (RSV), Human Metapneumovirus (HMPV), and Parainfluenza Virus (PIV) Vaccines

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

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is seeking Licensee(s) and/or a commercial collaborator(s) to further develop, test, and commercialize as live attenuated virus vaccines certain recombinant RSV, HMPV and/or PIV strains and associated intellectual property developed in the Laboratory of Infectious Diseases (LID), Division of Intramural Research, National Institute of Allergy and Infectious Diseases (NIAID).

DATES: Respondents interested in licensing the invention will be required to submit an ''Application for License to Public Health Service Inventions'' to NIH (attention Susan Ano, Ph.D. at the address mentioned below) on or before November 15, 2004, for priority consideration.

Potential CRADA collaborators must submit a letter summarizing their interests and capabilities to the NIAID (attention Richard K. Williams, Ph.D. at the address mentioned below) on or before November 15, 2004, for consideration. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest.

CRADA and PHS License Applications submitted thereafter may be considered if a suitable CRADA collaborator or Licensee(s) has not been selected.

FOR FURTHER INFORMATION CONTACT: Inquiries about these licensing opportunities should be addressed to Susan Ano, Ph.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 435–5515; facsimile: (301) 402–0220; e-mail: *anos@mail.nih.gov.* Information about Patent Applications and pertinent information not yet publicly described can be obtained under the terms of a Confidential Disclosure Agreement. Respondents interested in licensing the inventions will be required to submit an ''Application for License to Public Health Service Inventions''.

Depending upon the mutual interests of the Licensee(s) and the NIAID, a CRADA to collaborate to develop RSV, HMPV, and/or PIV vaccines in humans may also be negotiated. Proposals and questions about this CRADA opportunity should be addressed to Richard K. Williams, Ph.D., Technology Development Associate, Office of Technology Development, NIAID, 6610 Rockledge Drive, Room 4071, Bethesda, MD 20892–6606; telephone: (301) 402–0960; e-mail: *rwilliams@niaid.nih.gov.* Respondents interested in submitting a CRADA Proposal should be aware that it may be necessary to secure a license to the above-mentioned patent rights in order to commercialize products arising from a CRADA.

SUPPLEMENTARY INFORMATION: The portfolios listed below describe approaches to the development of live, attenuated vaccines for intranasal delivery against respiratory syncytial virus (RSV) subgroups A and B, human

metapneumovirus (HMPV), and three parainfluenza viruses (PIV1, –2, and –3), which account for up to 55–60% of serious respiratory tract infection in children and infants less than one year of age. Live attenuated viruses are the most promising candidate vaccines because they induce both local and systemic immunity and are efficacious even in the presence of passively transferred serum antibodies, the very situation found in the target population of infants with maternally derived antibodies.

These patents and patent applications describe broadly the generation of live attenuated vaccine viruses from recombinant cDNA clones for RSV, HMPV and PIV1, 2 and 3. For RSV and the PIVs, attenuation is achieved by missense mutations optimized for genetic stability, by gene deletion (*e.g.* E–089–1997; E–194–1999), by deletion of codons, by host range sequences (*e.g.* E–178–1999; E–201–2000; E–202–1999; E–187–1995), or by a combination of these (*e.g.* E–142–1996). HMPV has been attenuated by gene deletion (E–093–2003) and should be amenable to the other methods as well. Chimeras are described that contain the protective antigens of RSV subgroup B on an attenuated subgroup A background (*e.g.* E–178–1999), using a single attenuated backbone to make vaccines against both subgroups. Importantly, each of PIV viruses can be used as stable, efficient vectors for expressing the protective antigens of RSV, HMPV, or other viral pathogens in a schedule that permits boosting of immune responses (*e.g.* E–099–1999; E–089–1997; E–280–2001; E–092–2002). In this strategy, the PIV vector is a needed vaccine in addition to the expressed RSV/HMPV antigens, resulting in a bi- or multi-valent vaccine virus.

Augmentation of the immune response to the protective antigens can be achieved by positioning them in a more promoter proximal position (*e.g.* E–225–2000), by altering the regulation of viral transcription and replication by gene deletion, by deleting proteins that interfere with the host immune response, or by introducing an immunopotentiating molecule such as GM–CSF into the coding sequence of the vaccine virus (*e.g.* E–041–1999). Each of the viruses replicates efficiently in vitro, and stability of the attenuation phenotype can be achieved for each of the viruses described.

There are multiple approaches to the development of these live attenuated intranasal vaccines for RSV and PIV, making it possible for different parties to pursue unique approaches to vaccine development. The following patents and patent applications are available for licensing; certain virus vaccine strains are also available for licensing.

RSV Portfolio

1. E–123–1992/0,1,2

Attenuated Respiratory Syncytial Virus Vaccine Compositions

U.S. Patent 5,922,326 (issued July 13, 1999); U.S. Patent 6,284,254 (issued September 4, 2001); U.S. Patent 5,882,651 (issued March 16, 1999); PCT/US93/03670 (publication WO 93/21310) and all corresponding foreign rights.

2. E–187–1995/0,1,2

Production of Infectious Respiratory Syncytial Virus From Cloned Nucleotide Sequences

U.S. Patent 6,264,957 (issued July 24, 2001); PCT/US96/15524 (publication WO 97/12032) and all corresponding foreign rights.

3. E–142–1996/0–4

Production of Attenuated Respiratory Syncytial Virus Vaccines From Cloned Nucleotide Sequences

U.S. Patent 5,993,824 (issued November 30, 1999); U.S. Patent 6,689,367 (issued February 10, 2004); USSN 09/444,067 (filed November 19, 1999); USSN 09/444,221 (filed November 19, 1999); PCT/US97/12269 (publication WO 98/02530) and all corresponding foreign rights.

4. E–040–1999/0

Production of Attenuated Negative Stranded RNA Virus Vaccines From Cloned Nucleotide Sequences

USSN 09/958,292 (filed January 1, 2002); PCT/US00/09695 (publication WO 00/61737) and all corresponding foreign rights.

5. E–041–1999/0

Production of Recombinant Respiratory Syncytial Viruses Expressing Immune Modulatory Molecules

U.S. Patent 6,699,476 (issued March 2, 2004); USSN 10/031,095 (filed January 9, 2002); USSN 10/754,895 (filed January 8, 2004); PCT/US00/19042 (publication WO 01/04271) and all corresponding foreign rights.

6. E–194–1999/0

Production of Attenuated Respiratory Syncytial Virus Vaccines Involving Modification of M2 ORF2

U.S. Patent 6,713,066 (issued March 30, 2004).

7. E–178–1999/0,1,2

Production of Attenuated, Human-Bovine Chimeric Respiratory Syncytial Virus Vaccines (E–178–1999/0,1,2)

USSN 09/602,212 (filed June 23, 2000); USSN 10/030,951 (filed January 8, 2002); USSN 10/704,116 (filed November 7, 2003); PCT/US00/17755 (publication WO 01/04335) and all corresponding foreign rights.

8. E–225–2000/0

Respiratory Syncytial Virus Vaccines Expressing Protective Antigens From Promotor-Proximal Genes

USSN 09/887,469 (filed June 22, 2001); USSN 10/312,191 (filed December 20, 2002); PCT/US01/20107 (publication WO 02/00693) and all corresponding foreign rights.

PIV Portfolio

1. E–089–1997/2,3,4,5,6

Production of Parainfluenza Virus From Cloned Nucleotide Sequences

USSN 09/424,628 (filed April 5, 2000), USSN 09/083,793 (filed May 22, 1998), USSN 09/586,479 (filed June 1, 2000), USSN 09/459,062 (filed December 10, 1999); USSN 09/350,831 (filed November 9, 1999); U.S. Patent 6,410,023 (issued June 4, 2002); U.S. Patent 6,410,023 (issued June 25, 2002); PCT/US98/10551 (publication 98/53078), PCT/US00/18523 (publication WO 01/03744) and all corresponding foreign rights.

2. E–099–1999/0,1

Use of Recombinant Parainfluenza Viruses (PIVs) as Vectors To Protect Against Infection and Disease Caused by PIV and Other Human Pathogens

USSN 09/733,692 (filed December 8, 2000), PCT/US00/33293 (publication WO 01/42445) and all corresponding foreign rights.

3. E–202–1999/0

Attenuated Human-Bovine Chimeric Parainfluenza Virus (PIV) Vaccines

USSN 10/030,544 (filed January 8, 2002); PCT/US00/17066 (publication WO 01/04320) and all corresponding foreign rights.

4. E–201–2000/0

Attenuated Human-Bovine Chimeric Parainfluenza Virus (PIV) Vaccines

USSN 09/900,112 (filed July 5, 2001).

5. E–280–2001/0

Recovery of Recombinant Human Parainfluenza Virus Type 1 (HPIV1) from cDNA and Use of Recombinant HPIV1 as Vaccines and Vectors to Protect Against Infection and Disease Caused by PIV and Other Human Pathogens

USSN 10/302,547 (filed November 21, 2002); PCT/US02/37688 (publication WO 03/043587) and all corresponding foreign rights.

6. E–092–2002/0

Recovery of Recombinant Human Parainfluenza Virus Type 2 (HPIV) From cDNA and Use of Recombinant HPIV2 in Immunogenic Compositions and as Vectors To Elicit Immune Responses Against PIV and Other Human Pathogens

USSN 10/667,141 (filed September 18, 2003); PCT/US03/29685 (publication WO 2004/027037).

HMPV Portfolio

1. E–093–2003/0–2

Recovery of Recombinant Human Metapneumovirus (HMPV) From cDNA and Use of Recombinant HMPV in Immunogenic Compositions and as Vectors To Elicit Immune Responses Against HMPV and Other Human Pathogens

USSN 60/451,119 (filed February 28, 2003); USSN 60/478,667 (filed June 13, 2003); PCT/US04/05881 (filed February 27, 2004); and USSN 10/789,400 (filed February 27, 2004).

Dated: September 7, 2004.

Steven M. Ferguson,

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

[FR Doc. 04–20656 Filed 9–13–04; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; 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 Institute of Child Health and Human Development Initial Review Group Biobehavioral and Behavioral Sciences Subcommittee.

Date: November 15–16, 2004.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Contact Person: Marita R. Hopmann, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892, (301) 435–6911, *hopmannm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 2, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–20657 Filed 9–13–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Performance Partnership Grants (PPGs) Pilot Study for Performance Measures for Treatment of Co-occurring Disorders—New—SAMHSA's Center for Mental Health Services and Center for Substance Abuse Treatment will conduct a pilot study to examine the feasibility of collecting performance measures for treatment of co-occurring disorders. The pilot project will be conducted over a one-year period concluding at the close of 2005. Seven States with Co-occurring State Infrastructure Grants, and four additional non-grant States, together with multiple local sites within each of these States, will participate in the pilot project. Current data systems in each of the eleven States were reviewed in the first half of 2004, and actual data will be collected for the first two quarters of 2005. The balance of 2005 will be used for data analysis and report preparation, with recommendations for future steps.

Information will be collected about three performance areas: the number and percent of programs that offer screening, assessment, and treatment services for co-occurring disorders; the number of clients actually screened, assessed, and treated through these programs; and the effects of this care on client outcomes: reduction in symptoms and improved functioning, as well as better quality of life in the community.

If demonstrated to be feasible, these measures will subsequently be incorporated into the proposed set of performance measures for the mental health and substance abuse Performance Partnership Grants (PPGs). PPGs will be the next generation of block grants to be funded by SAMHSA, in which States will be granted additional program flexibility in return for reporting system performance measures.

Annual burden for the activities is shown below:

Activity	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Measure 1: State-level performance measures	730	2	0.45	650
Measure 2: Capacity to screen, assess, and treat	350	2	1.25	880
Measure 3: Outcomes	1,050	2	0.67	1,420
Total	2,130			2,950

Send comments to Summer King, SAMHSA Reports Clearance Officer, OAS, Room 7–1044, 1 Choke Cherry Road, Rockville, MD 20857. Written comments should be received by November 15, 2004.

Dated: September 8, 2004.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. 04–20687 Filed 9–13–04; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.