will be measured at baseline and at a final follow-up visit 15–24 months after the baseline visit. A DNA sample will be obtained once at the baseline visit to assess three key iron protein polymorphisms. Donors will also complete a self-administered survey assessing past blood donation, smoking history, use of vitamin/mineral supplements, iron supplements, aspirin, frequency of heme rich food intake, and, for females, menstrual status and pregnancy history at these two time points. This study aims to identify the optimal laboratory measures that would predict the development of iron depletion, hemoglobin deferral, and/or iron deficient hemoglobin deferral in active whole blood and double red cell donors at subsequent blood donations. The data collected will help evaluate hemoglobin distributions in the blood donor population (eligible and deferred donors) and compare them with NHANES data. Other secondary objectives include elucidating key genetic influences on hemoglobin levels and iron status in a donor population as a function of donation history; and establishing a serum and DNA archive to evaluate the potential utility of future iron studies and genetic polymorphisms.

This study will develop better predictive models for iron depletion and hemoglobin deferral (with or without iron deficiency) in blood donors; allow for the development of improved donor screening strategies and open the possibility for customized donation frequency guidelines for individuals or classes of donors; provide important baseline information for the design of targeted iron supplementation strategies in blood donors, and improved counseling messages to blood donors regarding diet or supplements; and by elucidating the effect of genetic iron protein polymorphisms on the development of iron depletion, enhance the understanding of the role of these proteins in states of iron stress, using frequent blood donation as a model.

Frequency of Response: Twice. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is a follows: *Estimated Number of Respondents:* Baseline visit: 2,340, Follow up Visit: 1,530; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* Baseline Visit: 0.37, Follow up Visit: 0.17; and *Estimated Total Annual Burden Hours Requested:* Baseline visit: 866, Follow up Visit: 260. The annualized cost to respondents is estimated at: Baseline Visit: $15,588, Follow up Visit: $4,680 (based on $18 per hour). There are no Capital Costs to report. There are no 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
Blood donors at Baseline Visit	2,340	1	0.37	866
Blood donors at Follow-up Visit	1,530	1	0.17	260
Total				1,126

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address 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 the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information 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 Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Suite 10042, 6701 Rockledge Drive, Bethesda, MD 20892–7950, or call 301–435–0075, or E-mail your request to *nemog@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: February 4, 2008.

George Nemo,

NHLBI Project Officer, NHLBI, National Institutes of Health.

[FR Doc. E8–2748 Filed 2–13–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Cooperative Research and Development Agreement (CRADA) Opportunity With the National Heart Lung and Blood Institute and Licensing Opportunity for Development of Multi-Domain Amphipathic Helical Peptides for the Treatment of Cardiovascular Disease

AGENCY: National Institutes of Health, PHS, HHS.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended, and in accordance with 35 U.S.C. 207 and 37 CFR Part 404, the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (HHS) seeks a Cooperative Research and Development Agreement (CRADA) and/or license(s) with a pharmaceutical or biotechnology company to develop and commercialize amphipathic helical peptides potentially useful for the treatment and prevention of cardiovascular disease. The CRADA would have an expected duration of one (1) to five (5) years. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, methods of treatment or prevention that may result from the research. The CRADA Collaborator will have an option to negotiate the terms of an exclusive or non-exclusive commercialization license to subject inventions arising under the CRADA defined by the CRADA Research Plan, subject to any pre-existing licenses already issued for other fields of use, and can apply for background licenses to the existing patent applications encompassed within HHS Reference Nos. E–114–2004/0–US–01 (United States Patent Application

Serial No. 11/577,259), E–114–2004/0–AU–03 (Australian Patent Application Serial No. 2005295640), E–114–2004/0–CA–04 (Canadian Patent Application No. 2584048), E–114–2004/0–EP–05 (European Patent Application No. 05815961.7) and E–114–2004/0–JP–06 (Japanese Patent Application No. 2007–536912) titled: Multi-Domain Amphipathic Helical Peptides and Methods of Their Use.

DATES: Inquiries regarding CRADA proposals and scientific matters may be forwarded at any time. Confidential preliminary CRADA proposals, preferably two pages or less, must be submitted to the NHLBI on or before April 14, 2008. Guidelines for preparing final CRADA proposals will be communicated shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest.

There is no deadline by which license applications must be received by the Office Technology Transfer however applicants are encouraged to respond on or before April 14, 2008. This notice replaces that published in the **Federal Register** on May 11, 2005 (70 FR 24832).

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Denise Crooks, Office of Technology Transfer and Development, NHLBI 6705 Rockledge Drive, MSC 7992, Bethesda, MD 20892 (phone: 301–402–5579, Fax: 391–594–3080, E-mail: *Crooksd@nhlbi.nih.gov*).

Scientific Inquiries should be directed to Dr. Alan T. Remaley, NHLBI, 10 Center Drive, Building 10, Room 2C–433, MSC 1508, Bethesda, MD 20892 (phone: 301–402–9796; fax: 301–402–1885; E-mail: *aremaley1@cc.nih.gov*).

Licensing inquiries and requests for license application should be directed to Ms. Fatima Sayyid, Technology Licensing Specialist, Office of Technology Transfer, NIH, 6011 Executive Blvd., Suite 325, Rockville, MD, 20852 (phone: 301–435–4521, Fax: 301–402–0220, E-mail: *Fatima.Sayyid@nih.hhs.gov*).

SUPPLEMENTARY INFORMATION:

Technology Available

HHS scientists within the Lipoprotein Metabolism Section (LMS), NHLBI, have discovered a novel class of non-hemolytic amphipathic synthetic peptides that are specific for effluxing excess cellular cholesterol by the ABCA1 transporter. These agents have been shown to significantly inhibit the progression of atherosclerosis in a mouse model of cardiovascular disease. Details are noted in HHS Reference #s E–114–2004/0–US–01 (United States Patent Application Serial No. 11/577,259), E–114–2004/0–AU–03 (Australian Patent Application Serial No. 2005295640), E–114–2004/0–CA–04 (Canadian Patent Application No. 2584048), E–114–2004/0–EP–05 (European Patent Application No. 05815961.7) and E–114–2004/0–JP–06 (Japanese Patent Application No. 2007–536912) titled: Multi-Domain Amphipathic Helical Peptides and Methods of Their Use. They are available for review under an appropriate Confidential Disclosure Agreement.

Technology Sought

Accordingly, HHS now seeks collaborative arrangements to provide more extensive biological and pharmacological evaluation of both current and any new amphipathic peptides that are being developed within the Lipoprotein Metabolism Section of NHLBI. The ultimate purpose of the collaboration would be to advance the most promising agents into clinical trials for the prevention and regression of cardiovascular disease. For collaboration with the private sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide for equitable distribution of intellectual property rights developed under the collaboration. CRADA aims will include rapid publication of research results as well as full and timely exploitation of commercial opportunities.

NHLBI and Collaborator Responsibilities

The role of LMS, NHLBI in this CRADA may include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.

2. Perform in conjunction with Collaborator *in vitro* studies to identify novel peptides.

3. Perform in conjunction with Collaborator animal studies on peptides with anti-atherosclerotic properties.

4. Provide the Collaborator with sequences of any novel peptides for future pharmaceutical development.

5. Planning and conducting research and clinical studies and interpreting research results.

6. Publishing research results.

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

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.

2. Planning scientific and clinical research studies and interpreting research results.

3. Providing some financial support for CRADA-related research as outlined in the CRADA Research Plan.

4. Publishing research results.

Selection criteria for choosing the CRADA Collaborator may include, but not be limited to:

1. The ability to collaborate with NHLBI on further research and development of this technology. This ability can be demonstrated through experience and expertise in this or related areas of technology indicating the ability to contribute intellectually to on-going research and development.

2. Expertise and experience in the following areas: Peptide design and synthesis, performance of preclinical studies including animal model studies of atherosclerosis, animal toxicology studies, knowledge of GMP grade production and scale up and lipid reconstitution of synthetic peptides, and design, U.S. Food and Drug Administration regulatory filings, and performance of clinical trials. The demonstration of adequate resources to perform the research, development and commercialization of this technology (e.g. facilities, personnel, expertise and funds) and accomplish objectives according to an appropriate timetable to be outlined in the CRADA Collaborators proposal.

3. The willingness to commit best efforts and demonstrated resources to the research, development and commercialization of this technology.

4. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.

5. The willingness to cooperate with the National Heart Lung and Blood Institute in the timely publication of research results.

6. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern the equitable distribution of patent rights to CRADA inventions. Generally, the rights of ownership are retained by the organization that is the employer of the inventor, with (1) the grant of a license for research and other Government purposes to the Government when the CRADA Collaborator's employee is the sole inventor, or (2) the grant of an option to elect an exclusive or non-exclusive license to the CRADA Collaborator when the Government employee is the sole or joint inventor.

Dated: February 7, 2008.

Steven M. Ferguson,

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

[FR Doc. E8–2750 Filed 2–13–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency 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.

Use of Amyloid Proteins as Vaccine Scaffolds

Description of Technology: Amyloid proteins are composed of peptides whose chemical properties are such that they spontaneously aggregate *in vitro* or *in vivo*, assuming parallel or antiparallel beta sheet configurations. Amyloid proteins can arise from peptides which, though differing in primary amino acid sequences, assume the same tertiary and quaternary structures. The amyloid structure presents a regular array of accessible N-termini of the peptide molecules.

Claimed in this application are compositions and methods for use of amyloid proteins as vaccine scaffolds, on which peptide determinants from microorganisms or tumors may be presented to more efficiently generate and produce a sustained neutralizing antibody response to prevent infectious diseases or treat tumors. The inventors have arrayed peptides to be optimally immunogenic on the amyloid protein scaffold by presenting antigen using three different approaches. First, the N-terminal ends of the amyloid forming peptides can be directly modified with the peptide antigen of interest; second, the N-termini of the amyloid forming peptides are modified with a linker to which the peptide antigens of interest are linked; and third, the scaffold amyloid may be modified to create a chimeric molecule.

Aside from stability and enhanced immunogenicity, the major advantages of this approach are the synthetic nature of the vaccine and its low cost. Thus, concerns regarding contamination of vaccines produced from cellular substrates, as are currently employed for some vaccines, are eliminated; the robust stability allows the amyloid based vaccine to be stored at room temperature for prolonged periods of time; and the inexpensive synthetic amino acid starting materials, and their rapid spontaneous aggregation *in vitro* should provide substantial cost savings over the resource and labor-intensive current vaccine production platforms.

Application: Immunization to prevent infectious diseases or treat chronic conditions or cancer.

Developmental Status: Vaccine candidates have been synthesized and preclinical studies have been performed.

Inventors: Amy Rosenberg (CDER/FDA), James E. Keller (CBER/FDA), Robert Tycko (NIDDK).

Patent Status: U.S. Provisional Application No. 60/922,131 filed 06 Apr 2007 (HHS Reference No. E–106–2007/0–US–01).

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Peter A. Soukas, JD; 301–435–4646; *soukasp@mail.nih.gov*.

Collaborative Research Opportunity: The FDA, Division of Therapeutic Proteins (CDER) and Office of Vaccines, Division of Bacterial Products (CBER) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize amyloid based vaccines for prevention of infectious disease or treatment of malignant states. Please contact Amy Rosenberg at *amy.rosenberg@fda.hhs.gov* or (301) 827–1794 for more information.

Inhibiting HIV Infection Using Integrin Antagonists

Description of Technology: Infection with HIV depletes and impairs CD4 cells, a key component of the immune system. Effective therapies such as highly active antiretroviral therapy (HAART) have focused on preserving CD4 cells. However, long term HAART has significant toxicity associated with it. The current technology describes the use of integrin antagonists as an alternative to treating or preventing HIV infection and replication. Specifically, α4 integrin plays a role in directing lymphocytes to the primary site of HIV replication. Inhibition of the interaction of α4β1 or α4β7 with gp120 can therefore be important in the development of effective HIV treatments.

Applications: Inhibiting HIV infection; Inhibiting HIV replication.

Development Status: In vitro data.

Inventors: James Arthos, Diana Goode, Claudia Cicala, and Anthony Fauci (NIAID).

Patent Status:

U.S. Patent Application No. 60/873,884 filed 07 Dec 2006 (HHS Reference No. E–055–2007/0–US–01)

U.S. Patent Application No. 60/920,880 filed 03 Mar 2007 (HHS Reference No. E–055–2007/1–US–01)

U.S. Patent Application No. 60/957,140 filed 21 Aug 2007 (HHS Reference No. E–055–2007/2–US–01)

PCT Patent Application No. PCT/US2007/086663 filed 06 Dec 2007 (HHS Reference No. E–055–2007/3–PCT–01)

Licensing Status: Available for exclusive or non-exclusive licensing.

Licensing Contact: Susan Ano, PhD; 301–435–5515; *anos@mail.nih.gov*.

Collaborative Research Opportunity: The NIAID Laboratory of Immunoregulation is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Dr. James Arthos at 301–435–2374 for more information.

Coacervate Microparticles Useful for the Sustained Release Administration of Therapeutics Agents

Description of Technology: The described technology is a biodegradable microbead or microparticle, useful for the sustained localized delivery of biologically active proteins or other molecules of pharmaceutical interest. The microbeads are produced from several USP grade materials, a cationic polymer, an anionic polymer and a binding component (e.g., gelatin, chondroitin sulfate and avidin), in predetermined ratios. Biologically active proteins are incorporated into preformed microbeads via an introduced binding moiety under nondenaturing conditions.