

Overview and Orientation to CDC, and the Biannual Tribal Consultation Session.

Times and Dates:

8 a.m.–5:30 p.m., February 26, 2008; TCAC Meeting.

8 a.m.–5:30 p.m., February 27, 2008; An Overview and Orientation to CDC.

8 a.m.–5:30 p.m., February 28, 2008; Biannual Tribal Consultation Session.

Place: Centers for Disease Control (CDC), 1600 Clifton Road NE, Atlanta, GA 30333, Telephone: 404–498–2343. Roybal Campus—Building 19, Room 206 Auditorium A.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

Purpose: CDC established the Tribal Consultation Policy in October of 2005 with the primary purpose of providing guidance across the agency to work effectively with American Indian/Alaska Native (AI/AN) communities and organizations to enhance AI/AN access to CDC programs. In October of 2005, an Agency Advisory Committee (CDC/ATSDR Tribal Consultation Advisory Committee—TCAC) was established to provide a complementary venue wherein tribal representatives and CDC staff will exchange information about public health issues in Indian Country, identifying urgent public health issues in Indian country, and discuss collaborative approaches to these issues. Within the CDC Consultation Policy, it is stated that CDC will conduct Government-to-government consultation with elected tribal officials or their designated representatives and also confer with tribal and Alaska Native organizations and AI/AN urban and rural communities before taking actions and/or making decisions that affect them. Consultation is an enhanced form of communication that emphasizes trust, respect, and shared responsibility. It is an open and free exchange of information and opinion among parties that leads to mutual understanding and comprehension. CDC believes that consultation is integral to a deliberative process that results in effective collaboration and informed decision making with the ultimate goal of reaching consensus on issues. Although formal responsibility for the agency's overall Government-to-government consultation activities rests within the Office of the Director, Coordinating Centers and Coordinating Offices, and center leadership shall actively participate in TCAC meetings and HHS-sponsored regional and national tribal consultation sessions as frequently as possible.

Matters To Be Discussed: The TCAC will convene their quarterly committee meeting with discussions and presentations from various CDC senior leadership on activities and areas identified by tribal leaders as priority public health issues. The Tribal Leaders Orientation Agenda has been established in response to tribal leaders' request to learn more about the CDC and its potential resources available. The Biannual Tribal Consultation Session will engage CDC Senior leadership from the Office of the Director and various CDC Offices and National Centers including the Financial Management Office, National Center for Environmental Health and the Agency for Toxic Substances, Coordinating Office for Terrorism and Preparedness and Emergency Response, National Center for Health Marketing, the Office of Chief of Public Health Practice, and the Office of Enterprise Communications. Opportunities will be provided during the Consultation Session for tribal testimony. Tribal Leaders are encouraged to submit written testimony by COB on February 8, 2008 to the contact person below. Depending on the time available it may be necessary to limit the time of each presenter.

Please reference this web link <http://www.cdc.gov/omhd/TCAC/AAC.html> to review information about the TCAC and CDC's tribal Consultation Policy.

For Further Information Contact: CAPT Pelagie (Mike) Snesrud, Senior Tribal Liaison for Policy and Evaluation, Office of Minority Health and Health Disparities, 1600 Clifton Road NE., MS E-67, Atlanta, Georgia 30333, telephone (404) 498–2343, fax (404) 498–2355, e-mail: pws8@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and Agency for Toxic Substances and Disease Registry.

Dated: February 6, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; comment request; The REDS-II Donor Iron Status Evaluation (RISE) Study

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 data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: *Title:* The REDS-II Donor Iron Status Evaluation (RISE) Study. *Type of Information Collection Request:* Revisions due to program adjustments. *Need and Use of Information Collection:* Although the overall health significance of iron depletion in blood donors is uncertain, iron depletion leading to iron deficient erythropoiesis and lowered hemoglobin levels results in donor deferral and, occasionally, in mild iron deficiency anemia. Hemoglobin deferrals represent more than half of all donor deferral, deferring 16% of women.

Several cross sectional studies of blood donors, using older measures of iron status in blood donors have indicated that female sex, frequent donation and not taking iron supplements are predictors of iron depletion. However, none of these studies have included racial/ethnic, anthropomorphic, or behavioral factors and none have evaluated the impact of newly discovered iron protein polymorphisms. The RISE Study is a longitudinal study of iron status in two cohorts of blood donors: A first time/reactivated donor cohort in which baseline iron and hemoglobin status can be assessed without the influence of previous donations, and a frequent donor cohort, where the cumulative effect of additional frequent blood donations can be assessed. Each cohort's donors will donate blood and provide evaluation samples during the study period.

The primary goal of the study is to evaluate the effects of blood donation intensity on iron and hemoglobin status and assess how these are modified as a function of baseline iron/hemoglobin measures, demographic factors, and reproductive and behavioral factors. Hemoglobin levels, a panel of iron protein, red cell and reticulocyte indices

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 as 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.
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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