III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.


Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–4139 Filed 2–22–12; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).
Dates and Times: March 8, 2012, 9 a.m. to 5 p.m. EST. March 9, 2012, 9 a.m. to 12:30 p.m. EST.
Place: Parklawn Building (and via audio conference call), Conference Room 10–45, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Thursday, March 8, from 9 a.m. to 5 p.m. (EST) and on Friday, March 9, from 9 a.m. to 12:30 p.m. (EST). The public can join the meeting via audio conference call by dialing 1–800–369–3104 (on March 8 & 9) and providing the following information:

Leader’s Name: Dr. Geoffrey Evans.
Password: ACCV.
Agenda: The agenda items for the March meeting will include, but are not limited to: Updates from the Division of Vaccine Injury Compensation (DVIC), the Department of Justice, the National Vaccine Program Office, the Immunization Safety Office (Centers for Disease Control and Prevention), the National Institute of Allergy and Infectious Diseases (National Institutes of Health), and the Center for Biologics, Evaluation, and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (http://www.hrsa.gov/vaccinecompensation/accv.htm) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in attending the meeting in person or providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or email: aherzog@hrsa.gov. Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by email, mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

FOR FURTHER INFORMATION CONTACT:
Anyone requiring additional information regarding the ACCV should contact Annie Herzog, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–6593; email: aherzog@hrsa.gov.


Reva Harris,
Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–4225 Filed 2–22–12; 8:45 am]
BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Opinions and Perspectives About the Current Blood Donation Policy for Men Who Have Sex With Men

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: Opinions and Perspectives about the Current Blood Donation Policy for Men Who Have Sex with Men. Type of Information Collection Request: New. Need and Use of Information Collection: The current policy for blood donation in the U.S. with respect to men who have sex with men (MSM) is that any man who discloses having had sex with another man since 1977 is deferred indefinitely from donating. However, data from donors who have tested disease marker positive and were interviewed regarding potential risk factors suggest that some individuals continue to donate blood without disclosing MSM activity in contravention of the policy. In the 1980s there were surveillance studies of risk factors among donors who were determined to be HIV positive in predonation testing: Results indicated MSM behavior to be a risk factor for 56% of male donors. In addition, as part of the Retrovirus Epidemiology Donor Study (REDS), when anonymously surveyed by paper and pencil mailed surveys, 1.2% of male blood donors reported MSM behavior.

In a 2007 study conducted in Sweden, 19% of 334 MSM who responded to a survey that was included in a monthly publication targeted to the Lesbian, Gay, Bisexual and Transgender (LGBT) community reported donating blood at least one-time since 1985. The authors suggested that MSM donors may be motivated by perceived discrimination, particularly younger MSM.

Recent publications from the United Kingdom have reported what are likely the only population-based assessment of non-compliance with a similar restriction on blood donation for the MSM population as in the U.S.; this
study was conducted in 2009 and 2010 and also estimated opinions about and self-reported intended compliance with the MSM deferral policy in place in the United Kingdom at that time. Note, the policy in the United Kingdom was modified in November 2011 and MSM in the United Kingdom are now allowed to donate if they have not been sexually active for a one-year period before donation.

Data similar to those collected in Sweden and the United Kingdom are not available for the U.S. Potential changes to the current MSM policy for blood donation requires additional data, including information about motivating factors and compliance with the current MSM policy or a modified policy in the MSM population and in current blood donors. Speculative analyses have been conducted but do not directly address important considerations related to this policy such as the current level of compliance (in the MSM population) and non-compliance (in the blood donor population). While many scientists and ethicists have expressed opinions in support or against modification of the current MSM policy for blood donation, there is a lack of data that directly addresses important aspects of this policy debate. The proposed study will build off the studies conducted in Sweden and the United Kingdom and will collect directly relevant information on this topic by estimating the prevalence of compliance and non-compliance with the current MSM policy and assessing motivations for blood donation in the U.S. MSM population.

Three research aims drive this study’s protocols to provide valuable evidence on the motivations and compliance behaviors in the MSM and blood donor populations. The four geographic areas where the study will be conducted include the State of Connecticut, Western Pennsylvania, Southern Wisconsin, and the Bay Area of California.

The first aim seeks to assess opinions about and common themes within the MSM population with respect to blood donation and the current MSM policy. Specifically, within a population of self-identified MSM in the U.S., what common themes can be identified regarding knowledge and opinions of current blood donation eligibility, and would opinions, including self-reported intended compliance, improve if the current MSM policy were changed to a deferral of a defined shorter duration? Another objective is to use what is learned in the focus groups to help select proper venues for identifying MSM who might be interested in participating in a comprehensive survey to assess compliance and non-compliance with the current MSM policy (see second aim).

The second aim seeks to assess compliance and non-compliance in the MSM population with the current MSM policy by confidentially surveying two populations. One survey will be conducted in the MSM community to provide better estimates of compliance and non-compliance with the current policy and a second survey will be conducted in male blood donors to evaluate how frequently men who have had sex with another man since 1977 are donating blood. The surveys will be conducted using an instrument that includes common content to maximize the comparability of the responses. Both surveys will be conducted using Internet-based techniques and currently available software (SurveyGizmo, www.surveygizmo.com).

The third aim seeks to assess motivations for donating in the group of self-identified MSM who are active blood donors in the U.S. Participants from the four geographic areas who report donating blood or the intention to donate will be asked to participate in confidential qualitative telephone interviews to identify their reasons for donating or wanting to donate blood.

Frequency of Response: Once.
Affected Public: Individuals. Type of Respondents: Males 18 years old or older. The annual reporting burden is as follows: Estimated Number of Respondents: 4864; Estimated Number of Responses per Respondent: 1 per respondent for 4844 respondents and 2 per respondent for 20 respondents; Average Burden of Hours per Response: 1.5 hours for Aim 1, 0.33 hour for Aim 2, and 1.0 hour for Aim 3; and Estimated Total Annual Burden Hours Requested: 1,700. The annualized total cost to all respondents is estimated at: $13,600 (based on $8.00 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

<table>
<thead>
<tr>
<th>Study Aims</th>
<th>Estimated Number of Respondents</th>
<th>Estimated Number of Responses per Respondent</th>
<th>Average Burden Hours per Response</th>
<th>Estimated Total Annual Burden Hours Requested</th>
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<tr>
<td>Aim 1—Focus Groups</td>
<td>64</td>
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<td>96</td>
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<td>Aim 2.1—Web interview</td>
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<td>Aim 2.2—Web interview</td>
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<td>Aim 3</td>
<td>*20</td>
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<td>1</td>
<td>20</td>
</tr>
</tbody>
</table>

* Aim 3 respondents are a subset of the respondents included in Aim 2.

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: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301–435–0065, or Email your request to: glynnsa@nhlbi.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.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Application for Collaboration With the NIH Center for Translational Therapeutics (NCTT)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Center for Advancing Translational Sciences (NCATS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on November 11, 2011, page 69743–69744 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Application for collaboration with the NIH Center for Translational Therapeutics (NCTT). Type of Information Collection Request: New. Need and Use of Information Collection: Programs at the NCTT provide opportunities to partner with and gain access to both common and specifically rare and neglected disease through a variety of programs delivering assay development, screening, hit to lead chemistry, lead optimization, chemical biology studies, drug development capabilities, expertise, and clinical/ regulatory resources in a collaborative environment with the goal of moving promising therapeutics into human clinical trials. NCTT uses an application and evaluation process to select collaborators. Selected investigators provide the drug project starting points and ongoing biological/disease expertise throughout the project. Frequency of Response: Once per year. Affected Public: Research scientists. Type of Respondents: not-for-profits, for-profit, governmental. The annual reporting burden is as follows: Estimated Number of Respondents: 170. Estimated Number of Responses per Respondent: 1. Average Burden Hours Per Response: 1. Estimated Total Annual Burden Hours Requested: 510.

ESTIMATES OF HOUR BURDEN

<table>
<thead>
<tr>
<th>Forms</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total annual burden hours</th>
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<td>Solicitation Instructions (TRND)</td>
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<tr>
<td>Total</td>
<td></td>
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<td></td>
<td>510</td>
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The annualized cost to respondents is estimated at: $21,261. Capital Costs are $0. Operating Cost is roughly $14,333 for the database to accept and coordinate responses.

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.

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, OIRA_submission@omb.eop.gov or by fax to 202–395–6974, 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. Helen Gift, Chief, Disease Prevention and Health Promotion Branch, DEODP, NIDCR, NIH, Natcher Building, Room 3AN–44D, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number 301–594–5579 or Email your request, including your address to: GiftH@de45.nidr.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.


John McKew,
Chief, Preclinical Development Branch, NIH Center for Translational Therapeutics, National Center for Advancing Translational Sciences, National Institutes of Health.

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 Institute of Child Health and