

highest priority and 5.0, lowest priority). Final grant award decisions will be made by the Deputy Assistant Secretary for Population Affairs (DASPA) on the basis of priority score, program relevance, and the availability of funds.

## VI. Award Administration Information

### 1. Notification of Award

The OPA does not release information about individual applications during the review process. When a final funding decision has been made, each applicant will be notified by letter of the outcome. The official document notifying an applicant that a project application has been approved for funding is the Notice of Grant Award, which specifies the amount of money awarded, the purpose of the grant, the length of the project period, and the terms and conditions of the award.

### 2. Administrative and National Policy Requirements

In accepting this award, the recipient stipulates that the award and any activities thereunder are subject to all provisions of 45 CFR parts 74 and 92, currently in effect or implemented during the period of the grant.

A Notice providing information and guidance regarding the "Government-wide Implementation of the President's Welfare-to-Work Initiative for Federal Grant Programs" was published in the **Federal Register** on May 16, 1997. This initiative was designated to facilitate and encourage grant recipients and their sub-recipients to hire welfare recipients and to provide additional needed training and/or mentoring as needed. The text of the Notice is available electronically on the OMB home page at <http://www.whitehouse.gov/omb>.

### 3. Reporting Requirement

At the completion of the project, the grant recipient must submit a brief summary in 2,500 to 4,000 words, written in non-scientific (laymen's) terms and Financial Status Report (SF-269). The narrative should highlight the findings and their implications for improving family planning service delivery. A plan for disseminating research findings should accompany the narrative. This plan should indicate how products of the research will be made accessible to the Office of Population Affairs, as well as to the Title X family planning administrators and practitioners, researchers, and State and local policy-makers. The summary, plan, and Financial Status Report must be mailed to the Grants Management Specialist identified on the Notice of

Grant Award within 90 days of the project's completion.

## VII. Agency Contacts

For information on specific research or program requirements, contact Eugenia Eckard, Office of Population Affairs, 1101 Wootton Parkway, Suite 700 Rockville, MD 20852, (301) 594-4001, or via e-mail at [eeckard@osophs.dhhs.gov](mailto:eeckard@osophs.dhhs.gov). For assistance on administrative and budgetary requirements, contact the OPHS Grants Management Office, 1101 Wootton Parkway, Suite 550, Rockville, MD, (301) 594-0758, or via e-mail at [kcampbell@osophs.dhhs.gov](mailto:kcampbell@osophs.dhhs.gov).

Dated: March 21, 2005.

### Alma L. Golden,

*Deputy Assistant Secretary for Population Affairs.*

[FR Doc. 05-5945 Filed 3-24-05; 8:45 am]

**BILLING CODE 4150-34-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Protection of Human Subjects, Proposed Criteria for Determinations of Equivalent Protection

**AGENCY:** Department of Health and Human Services, Office of the Secretary.

**ACTION:** Notice.

**SUMMARY:** The Office of Public Health and Science, Department of Health and Human Services (HHS) solicits public comment on criteria that have been recommended to the Office for Human Research Protections (OHRP) for making determinations of whether procedures prescribed by institutions outside the United States afford protections that are at least equivalent to those provided in the Federal Policy for the Protection of Human Subjects (codified by HHS as 45 CFR part 46, subpart A, and equivalent regulations of 14 Departments and Agencies, collectively referred to as the Federal Policy or the Common Rule).

**DATES:** Submit written or electronic comments on the recommended criteria for making determinations of equivalent protection on or before May 24, 2005.

**ADDRESSES:** Submit written comments to Ms. Gail Carter, Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, The Tower Building, Rockville, MD 20852, telephone number (301) 402-4521 (not a toll-free number). Comments also may be sent via facsimile to (301) 402-0527 or by e-mail to: [EQFRN@osophs.dhhs.gov](mailto:EQFRN@osophs.dhhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Glen Drew, Office for Human Research Protections, Office of Public Health and Science, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, (301) 402-4994, facsimile (301) 402-2071; e-mail: [gdrew@osophs.dhhs.gov](mailto:gdrew@osophs.dhhs.gov).

## SUPPLEMENTARY INFORMATION:

### I. Background

The HHS codification of the Federal Policy states at 45 CFR 46.101(h):

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a Department or Agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the Department or Agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the Department or Agency head, notices of these actions as they occur will be published in the **Federal Register** or will be otherwise published as provided in Department or Agency procedures.

No formal findings of equivalent protection have been published in the **Federal Register** since the Federal policy was finalized in June, 1991. Use of the authority provided by 45 CFR 46.101(h) has been advocated by various parties, including the National Bioethics Advisory Commission in its April, 2001 report "Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries," and the HHS Inspector General in the September, 2001 Report "The Globalization of Clinical Trials: A Growing Challenge in Protecting Human Subjects." The authority of the Secretary of Health and Human Services has been delegated to OHRP (68 FR 60392), and in considering use of the 45 CFR 46.101(h) authority, OHRP recognized a need for using consistent criteria as a basis for decisions regarding equivalent protections. During 2002, the OHRP Director established a working group of representatives from interested HHS agencies, with staff support from OHRP, to consider potential criteria for use in making such decisions. The working group delivered its report in July 2003. That report recommends a framework

for implementing the existing regulatory authority of 45 CFR 46.101(h). The full working group report recommends the approach and criteria described in this notice and is available at <http://www.hhs.gov/ohrp/international/EPWGReport2003.pdf> and the appendix table is available at <http://www.hhs.gov/ohrp/international/FPGWFramework.pdf>, or by request to either of the addresses given above.

## II. Request for Comments

OHRP has solicited and considered comments from the other agencies that have adopted the Federal Policy, and now solicits public comment on the working group's recommended criteria for making determinations whether procedures prescribed by institutions outside the United States provide protections that are at least equivalent to those provided by the Federal Policy. OHRP will consider all public comments in deciding whether, and if so how, to proceed with implementing the authority under 45 CFR 46.101(h). Draft guidance describing OHRP's proposed method of implementing this authority would be published for public comment before OHRP would issue final guidance on this topic.

OHRP neither endorses nor rejects the content, conclusions, or recommendations in the working group's report, but particularly solicits public comment on several questions related to the approach and criteria recommended in the report:

1. Is the recommended approach appropriate for implementing the authority under 45 CFR 46.101(h)?

1.a. Is it preferable to make determinations of equivalent protections on the basis of submissions by individual institutions or on the basis of national or international procedural standards that may be relied upon by multiple institutions without repeated assessments?

2. Could an alternative approach provide equal or greater effectiveness and efficiency for implementation of this authority?

2.a. If so, what approach and why would effectiveness or efficiency be improved?

3. Do the recommended criteria appropriately and adequately describe the protections provided to human subjects by the Federal Policy?

3.a. Do the regulatory provisions the working group cited as contributing to particular protections provided by the Federal Policy relate directly to those protections? (See Table 1.)

3.b. Should other regulatory provisions be cited as relating to particular protections?

3.c. What, if any, alterations or additions to the proposed criteria would be helpful in assessing whether procedures followed in foreign countries provide protections at least equivalent to those provided by the Federal Policy?

4. Is the procedure recommended by the working group for seeking a finding of equivalent protections under 45 CFR 46.101(h) appropriate?

## III. Framework Proposed in Working Group Report

The working group report concluded that

The primary focus of the U.S. policy is the accountability of the research institution for the welfare and rights of human subjects. The overarching goal of the specific accountability mechanisms and procedures described in the policy is to establish expectations of ethical conduct within the research institution. The responsibility for achieving these aims is shared by the institution, the Institutional Review Board (IRB), or Research Ethics Committee (REC), and the relevant U.S. Agency or Department head. Although investigators are critical actors in achieving these goals, the policy provides very little explicit guidance to investigators and therefore suggests that the protection of human subjects depends largely on the proper promotion and conscientious execution of standard practices and procedures, including those related to research ethics review, within the institution.

The working group proposed an approach to equivalent protections that involves five separate steps, the first of which is to identify the specific protections provided by 45 CFR part 46 subpart A, followed by three steps of determining the equivalence of the protections offered by the set of procedures employed in foreign research institutions, and the fifth step is to provide an assurance that these procedures will be followed within the institution.

### *Steps in determining equivalence.*

(1) Articulation of the specific protections embodied in 45 CFR part 46 subpart A.

(2) Assessment of the protections provided by the institution's procedures.

(3) Comparison of the protections provided by the institution's procedures with those provided by 45 CFR part 46 subpart A and determination whether or not the institution's procedures provide at least equivalent protections.

(4) Approval of the relevant department or agency head for the substitution of the institutional procedures in lieu of the procedures of 45 CFR part 46 subpart A.

### *Mechanism of assurance with OHRP.*

(5) Assurance from the institution that the substituted procedures will be

followed in the conduct of human subjects research funded by HHS. The assurance will be completed and filed with OHRP.

The working group identified 7 specific protections afforded by 45 CFR part 46 subpart A that it recommended be included in the determination of equivalence:

Establish norms of ethical conduct and due diligence in review and performance of research within the institution;

Ensure adequate authority and independence of the IRB/Research Ethics Committee;

Protect against biased decision making and arbitrary decisions in research ethics review;

Ensure sufficient quality and comprehensiveness of research ethics review;

Ensure research ethics review and oversight are commensurate with risks to research subjects and vulnerability of the study population;

Protect against unnecessary or unjustified risk throughout the course of the study; and

Ensure voluntary participation after adequate disclosure of information related to the study.

The working group concluded that each of these protections is necessary for a determination of equivalent protections. It also concluded that each protection may be achieved in a number of different ways, including the use of procedures that differ from those provided in 45 CFR part 46 subpart A.

In making determinations of equivalence, the working group recommended that OHRP assess whether the procedures employed by the foreign institution are able to satisfy each of these protections individually and in the aggregate.

The working group also recommended that, based on a recommendation from OHRP following a comparison of the protections provided by the institution's procedures and 45 CFR part 46 subpart A, the Secretary of HHS may find that the institution's procedures provide at least equivalent protections and approve the substitution of these procedures in lieu of those of 45 CFR part 46 subpart A. The working group concluded that a determination of equivalent protections does not affect OHRP's oversight authority for HHS funded research conducted within the institution. The working group considered the authority of OHRP to conduct on-going assessment of the equivalence of the institution's procedures and protections to be a protection implied in 45 CFR part 46 subpart A, though not part of the

assessment of the protections provided by an institution's procedures.

Similarly, the substitution of the institution's procedures in lieu of those of 45 CFR part 46 subpart A does not obviate the need for the institution to enter into an assurance with OHRP that the procedures will be followed by the institution in the conduct of HHS

funded research. An assurance is a legal promise to comply with certain conditions attached to the provision of U.S. federal research funding.

To show the relationship between the Federal Policy and each of the seven protections the working group discerned in the Federal Policy, it developed a table matching the protections with

provisions of 45 CFR part 46 subpart A that contribute to each of the protections. The center column of the table provides examples of procedures that the working group thought institutions might use to provide the protection related to those regulatory provisions. The table appears below.

**Appendix**

TABLE 1.—FRAMEWORK FOR EQUIVALENT PROTECTIONS

Specific protection	Example procedures	45 CFR part 46 subpart A authority
<b>INSTITUTIONAL RESPONSIBILITIES</b>		
<p>Establish norms of ethical conduct and due diligence in review and performance of research within the institution.</p>	<ul style="list-style-type: none"> <li>—Institutional statement of principles.</li> <li>—Procedures for review .....</li> <li>—Procedures for reporting to Research Ethics Committee (REC).</li> <li>—Procedures for REC record keeping.</li>   <li>—Statement of investigator responsibilities.</li> <li>—Effective dissemination of REC submission procedures.</li> <li>—Investigator training .....</li> </ul>	<p>46.103(a); 46.103 (f) Establish and satisfy terms of assurance.</p> <p>46.103(b)(1) Develop or adopt statement of principles governing institution's human subjects protections responsibilities.</p> <p>46.103(b)(4) Ensure initial and continuing review of research; determine necessary frequency of review for each study; determine where external verification is necessary that no material changes have occurred since last IRB review; establish procedures for IRB reporting of findings and actions to institution and investigator(s).</p> <p>46.103(b)(5) Establish and 46.108 (a) follow written procedures for prompt reporting to IRB and Institutional officials of:</p> <ul style="list-style-type: none"> <li>—Unanticipated problems involving risk to subjects or others, or non-compliance with the policy;</li> <li>—Suspension or termination of IRB approval.</li> </ul> <p>46.103(b)(4) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.</p> <p>46.103(b)(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.</p> <p>46.115 An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities. The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Department or Agency at reasonable times and in a reasonable manner.</p>
<p>Ensure adequate authority, and independence of IRB.</p>	<ul style="list-style-type: none"> <li>—Documentation of REC authority</li> </ul>	<p>46.109(a); 46.109 (e) grant and ensure necessary authority for IRB, including: discretion to review, approve, require modifications, or disapprove research activities; increase information for informed consent, observe, or have third party observe consent process and research.</p> <p>46.112 Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.</p> <p>46.113 An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.</p> <p>46.110(b) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).</p>

TABLE 1.—FRAMEWORK FOR EQUIVALENT PROTECTIONS—Continued

Specific protection	Example procedures	45 CFR part 46 subpart A authority
	—REC member(s) unaffiliated with the institution.	46.107(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
<b>Research Ethics Committee (REC) Responsibilities</b> <i>Appropriate Scope and Quality of Review:</i>		
Protect against biased decision making and arbitrary decisions in research ethics review.	<p>—Public accessibility of REC membership and affiliation within institution.</p> <p>—Institutional policy on REC conflict of interest.</p> <p>—REC membership to reflect: independence, unaffiliated member(s).</p>	<p>46.103(b)3 A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations. Disclosure of any employment or other relationship between each [IRB] member and the institution.</p> <p>46.107(a) IRB membership. (see 45 CFR 46 for specific criteria).</p> <p>46.107(b) Gender balance.</p> <p>46.107(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.</p> <p>46.107(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.</p> <p>46.107(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.</p>
Ensure sufficient quality and comprehensiveness of review.	—REC membership to reflect competence, comprehensiveness of review; adequate expertise for study population; diversity of representation; gender balance.	<p>46.107(b) Gender balance.</p> <p>46.107(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.</p> <p>46.107(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.</p> <p>46.107(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.</p> <p>46.108(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.</p>
Ensure research ethics review and oversight are commensurate with risks to research subjects and vulnerability of the study population.	<p>—Procedures for continuing review and monitoring commensurate with risk.</p> <p>—Procedures for evaluating risk and benefit.</p> <p>Procedures for reviewing selection of subjects and safeguards provided.</p> <p>—Procedures for IRB reporting to investigators.</p>	<p>46.109(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.</p> <p>46.110(b) Expedited Review.</p> <p>46.111(a)(2) In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.</p> <p>46.111(a)(3) Selection of subjects as equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.</p> <p>46.113 Any suspension or termination or approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head.</p>

TABLE 1.—FRAMEWORK FOR EQUIVALENT PROTECTIONS—Continued

Specific protection	Example procedures	45 CFR part 46 subpart A authority
Protect against unnecessary or unjustified risk throughout the course of the study.	<p>—REC membership policy reflects adequate expertise and experience.</p> <p>—Policy has provisions for supplementing expertise, experience and disciplinary perspective as required.</p> <p>—Procedures for review of minimization of risk.</p> <p>—Procedures for reviewing selection of subjects and safeguards provided.</p> <p>—Procedures for continued oversight and monitoring.</p>	<p>46.107(a) If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.</p> <p>46.111(a)(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.</p> <p>46.111(a)(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.</p> <p>46.111(a)(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.</p> <p>46.111(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.</p> <p>46.111(a)(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.</p> <p>46.109(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.</p>
Ensure voluntary participation after adequate disclosure of information related to the study.	<p>—Policies on obtaining verifiable informed consent.</p> <p>—Policies on types of information to be disclosed in the informed consent process.</p>	<p>46.116 Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.</p> <p>46.111(a)(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.</p> <p>46.111(a)(5) Informed consent process will be appropriately documented, in accordance with, and to the extent required by § 46.117.</p> <p>46.116 The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.</p> <p>46.117(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative.</p> <p>46.109(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.</p> <p>46.109(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.</p> <p>46.109(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.</p>

TABLE 1.—FRAMEWORK FOR EQUIVALENT PROTECTIONS—Continued

Specific protection	Example procedures	45 CFR part 46 subpart A authority
		46.111(a)(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116. 46.116(a)(1–8) Necessary elements of disclosure. 46.116(b)(1–6) Necessary elements of disclosure. 46.116(c)(1–2) Waiver of informed consent. 46.116(d)(1–4) Approval of alternate consent procedures or waiver. 46.117(a) Written informed consent.

**Bernard A. Schwetz,**

Director, Office for Human Research Protections.

[FR Doc. 05–5947 Filed 3–24–05; 8:45 am]

BILLING CODE 4150–36–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### The National Center for Chronic Disease Prevention and Health Promotion

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention announces the following meeting.

*Name:* Interagency Committee on Smoking and Health.

*Time and Date:* 9 a.m.–4:30 p.m., April 13, 2005.

*Place:* Omni Shoreham Hotel, Hampton Ballroom, 2500 Calvert Street, NW., Washington, DC 20008. Telephone: 202–234–0700.

*Status:* Open to the public, limited only by the space available. Those who wish to attend are encouraged to register with the contact person listed below. If you will require a sign language interpreter, or have other special needs, please notify the contact person by 4:30 e.s.t. on April 4, 2005.

*Purpose:* The Interagency Committee on Smoking and Health advises the Secretary, Department of Health and Human Services, and the Assistant Secretary for Health in the (a) coordination of all research and education programs and other activities within the Department and with other Federal, State, local and private agencies and (b) establishment and maintenance of liaison with appropriate private entities, Federal agencies, and State and local public health agencies with respect to smoking and health activities.

*Matters to be Discussed:* The agenda will focus on addressing the Global Tobacco Epidemic.

*For Further Information Contact:* Substantive program information as well as summaries of the meeting and roster of committee members may be obtained from the Internet at <http://www.cdc.gov/tobacco> in mid-May or from Ms. Monica L. Swann, Management and Program Analyst, Office on

Smoking and Health, 200 Independence Avenue, SW., Suite 317B, Washington, DC 20201, (202) 205–8500.

Agenda items are subject to change as priorities dictate.

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 Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 18, 2005.

**Alvin Hall,**

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

[FR Doc. 05–5913 Filed 3–24–05; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, National Center for Infectious Diseases

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

*Name:* Board of Scientific Counselors, National Center for Infectious Diseases (NCID).

*Times and Dates:* 9 a.m.–5:30 p.m., May 12, 2005. 8:30 a.m.–2 p.m., May 13, 2005.

*Place:* CDC, Auditorium B, Building 1, 1600 Clifton Road, Atlanta, Georgia 30333.

*Status:* Open to the public, limited only by the space available.

*Purpose:* The Board of Scientific Counselors, NCID, provides advice and guidance to the Director, CDC, and Director, NCID, in the following areas: program goals and objectives; strategies; program organization and resources for infectious disease prevention and control; and program priorities.

*Matters To Be Discussed:* Agenda items will include:

1. Opening Session: NCID Update.
2. Futures Initiative Update.
3. Environmental Microbiology.

4. Development of CDC Research Agenda.  
5. Veterinary-Human Public Health Interface.

6. Global Disease Detection Initiative.

7. Topic Updates.

a. Influenza.

b. Chronic Wasting Disease.

c. Quarantine Update.

8. Board meets with Director, CDC.

Other agenda items include announcements/introductions; follow-up on actions recommended by the Board December 2004; consideration of future directions, goals, and recommendations.

Agenda items are subject to change as priorities dictate.

Written comments are welcome and should be received by the contact person listed below prior to the opening of the meeting.

*Contact Person for More Information:* Tony Johnson, Office of the Director, NCID, CDC, Mailstop E–51, 1600 Clifton Road, NE., Atlanta, Georgia 30333, e-mail [tjohnson3@cdc.gov](mailto:tjohnson3@cdc.gov); telephone 404/498–3249.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 18, 2005.

**Alvin Hall,**

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

[FR Doc. 05–5909 Filed 3–24–05; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS–2211–N]

#### Medicare, Medicaid, and CLIA Programs; Continuance of the Approval of the American Society for Histocompatibility and Immunogenetics as a CLIA Accreditation Organization

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.