

- a. Fiscal Year 2007 Results.
- b. Fiscal Year 2008 Budget.
- c. Fiscal Year 2009 Estimate.

#### Parts Closed to the Public

#### 6. Personnel.

**CONTACT PERSON FOR MORE INFORMATION:** Thomas J. Trabucco, Director, Office of External Affairs, (202) 942-1640.

Dated: August 31, 2007.

**Thomas K. Emswiler,**

*Secretary to the Board, Federal Retirement Thrift Investment Board.*

[FR Doc. 07-4350 Filed 8-31-07; 11:45 am]

**BILLING CODE 6760-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Request for Information and Comments on Research That Involves Adult Individuals With Impaired Decision-making Capacity

**AGENCY:** Office for Human Research Protections, Office of Public Health and Science, Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** The Office for Human Research Protections (OHRP), Office of Public Health and Science is seeking information and comments about whether guidance or additional regulations are needed to adequately protect adult individuals with impaired decision-making capacity who are potential subjects in research. This request for information and comments stems from the recommendation of an HHS working group, generated in response to the report published by the National Bioethics Advisory Commission (NBAC) entitled "Research Involving Persons With Mental Disorders That May Affect Decision-making Capacity" (December 1998), and from subsequent recommendations by the National Human Research Protections Advisory Committee (NHRPAC).<sup>a</sup>

In addition, as part of its charge to provide expert advice and recommendations to the Secretary of Health and Human Services (the Secretary) and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human subjects, the Secretary's Advisory Committee on Human Research Protections (SACHRP) has formed a Subcommittee on Inclusion of Individuals with Impaired

Decision-Making in Research. This SACHRP subcommittee is currently considering whether guidance or additional regulations are needed for research involving individuals with impaired decision-making capacity. The information and comments submitted in response to this notice will be shared with SACHRP to inform the Committee's recommendations to the Secretary and Assistant Secretary for Health.

**DATES:** Submit written or electronic information and comments by December 4, 2007.

**ADDRESSES:** Submit written comments to **REQUEST FOR INFORMATION ON RESEARCH THAT INVOLVES ADULT INDIVIDUALS WITH IMPAIRED DECISION-MAKING CAPACITY**, Office for Human Research Protections, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments also may be sent via e-mail to [impairedcapacityohrp@hhs.gov](mailto:impairedcapacityohrp@hhs.gov), or via facsimile at 301-402-2071. Comments received within the comment period, including any personal information provided, will be made available to the public upon request.

**FOR FURTHER INFORMATION CONTACT:** Julie Kaneshiro, Office for Human Research Protections, Department of Health and Human Services, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; 240-453-6900; e-mail [julie.kaneshiro@hhs.gov](mailto:julie.kaneshiro@hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Department of Health and Human Services (HHS) regulates research involving human subjects conducted or supported by HHS through regulations codified at 45 CFR part 46 which are administered by OHRP. The HHS regulations stipulate that in order to approve research covered by the regulations, an institutional review board (IRB) shall determine that 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. 45 CFR 46.111(b). Apart from this broad requirement regarding vulnerable populations, the HHS regulations do not contain specific additional standards for the participation of adults with impaired decision-making capacity in research, nor do they define who should be considered as part of this population.

In response to the recommendations by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) that pertained to research involving individuals who are institutionalized as mentally infirm, in 1978, the Department of Health, Education, and Welfare (now HHS), issued proposed regulations on research involving those institutionalized as mentally disabled. However, these proposed regulations were never finalized or adopted due to a lack of consensus on the proposed regulatory provisions, and a judgment that the general HHS regulations governing human subjects' participation in research were sufficient to address the National Commission's recommendations.

The impetus for this request for information and comments stems from a number of different sources. HHS is aware that some research currently conducted or supported by HHS involves adults with impaired decision-making capacity. HHS believes that research involving adults with impaired decision-making capacity is important and necessary in order to improve the health and well-being of such individuals. HHS and others have long recognized the potential vulnerability of these subjects, and that research involving this population needs to be conducted with adequate safeguards. At this time HHS believes it is appropriate to solicit the views of the public on whether the current human subject protection regulations are adequate in safeguarding these individuals. This request for information and comments also stems from recommendations of an HHS working group (HHS WG), generated in response to the report published by the former NBAC entitled "Research Involving Persons with Mental Disorders That May Affect Decision-making Capacity" (December 1998), and from subsequent recommendations by the former NHRPAC.

##### *A. NBAC Report*

In its December 1998 report, the full text of which can be found on the Internet at <http://bioethics.georgetown.edu/nbac>, NBAC defined decisional impairment as a limitation or incapacity that is not part of normal growth and development. NBAC's report contained recommendations for helping to ensure adequate protections for people with decisional impairment who participate in research, but referred only to research involving persons with mental disorders

<sup>a</sup> The National Human Research Protections Advisory Committee has been disbanded and replaced by the Secretary's Advisory Committee on Human Research Protections.

that may affect decision-making capacity.

NBAC's recommendations called for a new regulatory framework requiring IRBs to classify into one of three categories all proposed research that involves people with impaired decision-making capacity due to mental disorders, based on the level of risk and potential for direct medical benefit to the research subject. NBAC identified three categories of research that pose: (1) Minimal risk to subjects; (2) greater than minimal risk to subjects and having the prospect of direct medical benefit; and (3) greater than minimal risk to subjects but having no prospect of direct medical benefit. NBAC recommended that the legally authorized representative of a subject with impaired decision-making capacity be able to give permission for the subject's participation in research protocols that fall into either of the first two categories. However, NBAC recommended that research in the third category could not proceed unless one of two conditions occurred: Either (1) the research subject would have had to give Prospective Authorization for the particular class of research when competent, or (2) a Special Standing Panel (SSP), convened by the Secretary of HHS, would need to review the research and find it approvable or have issued guidelines about the class of research indicating that it was approvable. In NBAC's recommendations, Prospective Authorization would provide individuals, when competent, with an opportunity to express their preferences (if they have them) regarding future research participation, within certain limits. NBAC recommended that a Prospective Authorization should specify the "particular class of research," and the degree of specificity in the Prospective Authorization should be correlated with the level of risk posed by the research. For example, a person with a diagnosis of early stage Alzheimer's Disease who is still competent to make decisions could express his or her preference to participate in greater than minimal risk clinical trials testing interventions for moderate or severe Alzheimer's Disease in the future, when he or she may not be competent to make decisions.

#### B. HHS Working Group

The Office of Science Policy, Office of the Assistant Secretary for Planning and Evaluation, convened an HHS WG to analyze NBAC's recommendations and to develop a proposed HHS response to the NBAC report. The HHS WG's report can be found on the Internet at <http://aspe.hhs.gov/sp/human.shtml>. The HHS

WG considered, among other things, NBAC's recommended framework described above. The HHS WG was concerned that this framework was not practical because it would lead to the use of either a Prospective Authorization or a SSP for a large number of research protocols involving subjects with impaired decision-making capacity. The HHS WG concluded that the widespread use of Prospective Authorizations is unlikely. Thus, unless the research involved the prospect of direct medical benefit to the participants, an SSP would need to review all research involving greater than minimal risk.

The HHS WG compared NBAC's proposed regulatory framework to the HHS regulations governing the participation of children in research (45 CFR part 46 subpart D [hereafter referred to as "subpart D regulations"]). The subpart D regulations allow an IRB to consider a broad range of different types of direct benefits to the subject, not just direct medical benefits, when weighing the risks posed by research involving greater than minimal risk that presents the prospect of direct benefit to the individual child. NBAC, on the other hand, recommended that benefits be limited to direct medical benefits only for research involving subjects with impaired decision-making capacity. The subpart D regulations also create an intermediate risk category, not included in NBAC's framework, called a "minor increase over minimal risk." The HHS WG noted that an alternative regulatory framework modeled on subpart D could provide appropriate protection and also decrease the number of studies needing SSP review and thus may increase the feasibility of such reviews.

The HHS WG decided that NBAC's recommended framework would limit an IRB's authority to approve research involving an adult with impaired decision-making capacity more than it would an IRB's authority to approve a child's participation in the same type of research. The HHS WG further noted that NBAC's framework would alter IRB authority in ways that could produce different results. For example, the subpart D regulations permit a child's parent or guardian to enroll the child in research that has no prospect of direct benefit and that poses a minor increase over minimal risk if an IRB determines the research, among other things, is "likely to yield generalizable knowledge \* \* \* of vital importance" about the child's disorder or condition (45 CFR 46.406). However, under NBAC's recommendations, the legally authorized representative of an adult

with impaired decision-making capacity could not enroll the adult in the same type of research, unless the adult had signed a Prospective Authorization or the SSP approved or issued guidelines about the research. The HHS WG recognized that safeguards for children and adults with impaired decision-making capacity need not necessarily be identical, but noted that two different standards might be confusing to investigators and IRBs.

In addition, in its 1998 report, NBAC considered how ethically acceptable research could be conducted with human subjects who suffer from mental disorders that may affect their decision-making capacity. The HHS WG interpreted the intended scope of NBAC's recommendations as applying to research involving "persons with mental disorders that may affect decision making capacity," but determined that the scope of NBAC's recommendations seem appropriately applicable to research involving adults with decisional impairment, irrespective of the cause. The HHS WG noted that some physical disorders or conditions (e.g., cancer, sepsis, head injury) also might result in impaired capacity to make decisions, and therefore, an inability to give voluntary informed consent to participate in research. In addition, the HHS WG was concerned that limiting the scope of protections to research subjects whose decision-making capacity is impaired because of a mental disorder may be perceived to be stigmatizing to such individuals. Thus, the HHS WG concluded that adults with an impaired capacity to make a decision as a result of any disease or condition should receive the same protections as those individuals with an impaired decision-making capacity from a mental disorder.

The HHS WG proposed that OHRP request public comment on the issues raised by the NBAC framework and the HHS WG's analysis of those issues. This request for information and comments is designed to accomplish that goal.

#### C. NHRPAC Report

In response to NBAC's recommendations and the HHS WG's report, at OHRP's request, NHRPAC drafted a report entitled "Informed Consent and the Decisively Impaired." NHRPAC was an advisory committee to the Secretary of HHS, the Assistant Secretary for Health, the Director of OHRP, and other Departmental officials on a broad range of issues and topics pertaining to or associated with the protection of human research subjects. NHRPAC's draft report is available on the Internet at

<http://www.hhs.gov/ohrp/nhrpac/documents/nhrpac10.pdf>. NHRPAC's report applies to "all potential subjects in biomedical and social/behavioral research who lack decisional capacity for any reason and is not limited to persons with mental disorders." In its report, NHRPAC recommended specific protections at different levels of risk and potential benefit for research with the decisionally impaired population. These risk-benefit categories included:

(1) Research that involves no more than minimal risk,

(2) Research that involves greater than minimal risk but presents the prospect of direct benefit to the subjects,

(3) Research that involves a minor increase over minimal risk that does not present the prospect of direct benefit but is likely to yield generalizable knowledge about the subject's condition or disorder, and

(4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of persons with impaired decision-making capacity, provided the Secretary of HHS makes specified determinations after consulting with a panel of experts and providing the opportunity for public review and comment.

These risk categories are similar to those contained in the subpart D regulations governing research with children.

#### D. SACHRP Activities

In October 2002, SACHRP was created by the Secretary to replace NHRPAC. SACHRP is charged to advise, consult with, and make recommendations to the Secretary and Assistant Secretary for Health on matters pertaining to the continuance and improvement of functions within the authority of HHS directed toward protections for human subjects in research. In carrying out its charge, SACHRP formed a Subcommittee on Inclusion of Individuals with Impaired Decision-Making Capacity in Research. Specifically, this SACHRP subcommittee will develop recommendations for consideration by SACHRP about whether guidance or additional regulations are needed for research involving individuals with impaired decision-making capacity. In making its assessment, the Subcommittee will review the relevant provisions of subpart A, 45 CFR part 46, including the provisions at 45 CFR 46.111(b), and will seek additional information to formulate its decision as it deems necessary.

The information and comments submitted in response to this notice will be shared with SACHRP to inform the Committee's recommendations to the Secretary and Assistant Secretary for Health.

The reports of the National Commission, NBAC, and NHRPAC specifically address and endorse the inclusion of decisionally incapacitated subjects in clinical research with the provision of adequate protections for these subjects. Based on these recommendations and reports over the years, and SACHRP's current work on this issue, OHRP is seeking comment on whether it is necessary to develop additional safeguards to protect adult individuals with impaired decision-making capacity because these individuals may have diminished or no capacity to provide informed consent to their participation in research. The next section contains the specific questions of interest to HHS.

## II. Request for Information and Comments

OHRP is seeking information and comments from the public about whether guidance or additional regulations are needed to adequately protect adult individuals with impaired decision-making capacity who are potential subjects in research. The scope of this request for information and comments is limited to research involving adult subjects because additional protections for children involved as subjects in research already exists under the subpart D regulations. In addition, this notice is not directed toward consideration of emergency research involving the decisionally impaired that would be covered under the HHS's Secretarial waiver under 45 CFR 46.101(i) on the exception from informed consent requirements for emergency research (published in the **Federal Register** in 1996 at 61 FR 51531). OHRP believes that this existing provision already addresses the conduct of emergency research without informed consent that involves individuals with impaired decision-making capacity.

OHRP specifically seeks information and comments on the following issues. Comments should also include a reference to the specific numbered question being addressed:

1. What are investigators' and IRBs' current practices in regard to the conduct, review, and approval of research involving decisionally impaired adult individuals?

1a. Have investigators' or IRBs' practices changed as a result of NBAC's or NHRPAC's recommendations? If not, why not?

1b. If an IRB regularly reviews research proposals involving adult individuals with impaired decision-making capacity, do such IRBs include one or more members or consultants who are familiar with conditions that may affect decision-making capacity and with the concerns of the population being studied?

1c. Are investigators proposing research targeting adult individuals with impaired decision-making capacity as subjects providing IRBs with a thorough justification for their proposed research design, including a description of the procedures that are designed to minimize risks to subjects?

1d. If research protocols targeting adult individuals with impaired decision-making capacity as subjects are being approved by IRBs when the research could be done with other subjects, what are the reasons for IRBs approving such studies?

1e. Are investigators proposing research targeting adult individuals with impaired decision-making capacity as subjects providing IRBs with a thorough evaluation of the risks and potential benefits to the subjects involved in the proposed research study?

1f. For research involving adult individuals with impaired decision-making capacity as subjects, how are subjects' potential or actual objections to enrollment or continued participation in research being addressed by investigators and IRBs?

1g. Are IRBs requiring investigators to have an assessment of a potential subject's capacity to consent, and if so, under what circumstances? If IRBs are requiring capacity assessments for some research, is the degree of risk presented by the research pertinent to the IRB's decision to require such assessments? What concerns have arisen in regard to capacity assessments?

1h. For studies that have included an assessment of potential subjects' capacity to consent, how has this assessment been used in the informed consent process? Are subjects notified when they have been found to lack capacity to consent? When informed consent is sought from such a subject's legally authorized representative, are potential subjects provided an opportunity to assent or object to their participation in the research?

1i. For research involving subjects who are able to provide informed consent, but are expected to have fluctuating, limited, or diminishing decision-making capacity during the course of the research study, what processes or procedures have investigators implemented, or have IRBs

required, in order to ensure that the rights and welfare of such subjects remains adequately protected?

2. What problems or concerns have arisen for investigators, IRBs, or research subjects in the conduct or review of research involving decisionally impaired individuals as subjects?

2a. To what extent, if any, has the absence of OHRP guidance or additional regulatory requirements given rise to unacceptable practices by IRBs or investigators reviewing or conducting research targeting adult individuals with impaired decision-making capacity as subjects, or created inappropriate barriers to the conduct of research involving individuals with impaired decision-making capacity as subjects?

2b. Please describe the process used when a legally authorized representative is asked to consent on behalf of a prospective research subject for research involving adult individuals with impaired decision-making capacity as subjects. Do the legally authorized representatives use substituted judgment (decisions that reflect the views of the individual expressed while decisionally capable) or the best interest standard? Which seems more ethically justified?

2c. How are advance directives for health care and for research used when a legally authorized representative is available?

2d. Have any problems or concerns arisen in regard to seeking consent from a legally authorized representative on behalf of a prospective research subject for research involving adult individuals with impaired decision-making capacity as subjects? If so, please describe the issues that have arisen.

3. The current requirement for IRB approval under the HHS regulations at 45 CFR 46.111(b), states:

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.

Please describe the additional safeguards you have included in studies to protect the rights and welfare of subjects with impaired decision-making capacity.

3a. Does the regulatory provision cited above provide sufficient protections for adult subjects with impaired decision-making capacity or are additional regulatory safeguards needed? If additional safeguards are needed, what should these additional protections be? Below please find a

compendium of possible additional protections for subjects with impaired decision-making capacity. Please feel free to comment on any or all of them, and to suggest others. In your comments, please indicate if your comments are directed towards the issuance of either guidance or additional regulations:

- Consent auditor/independent consent monitor.
- Sliding scale of capacity, (i.e., protections should be proportional to the severity of capacity impairment, or to the magnitude of experimental risk, or both).
- Description of specific tasks to assess capacity (these may be study-specific).
- Independent assessment of decision-making capacity.
- Enhancement of IRB expertise such that the IRB includes members or consultants familiar with conditions that may affect decision-making capacity and with the concerns of the population being studied.
- Obtaining consent from legally authorized representative.
- Obtaining assent from subjects with impaired decision-making capacity (may be limited to objecting to inclusion in the research study). This would be in addition to consent from the legally authorized representative.
- Use of advance directive for research where permitted by state/local law.
- Use of appropriate waiting periods (after research presented to the subject) before obtaining assent or consent as possible.
- Consent enhancements: Interventions to increase the subject's decision-making capacity.
- Other suggestions.

3b. If the regulations at 45 CFR part 46 are sufficient, should OHRP issue additional guidance on how the regulations should be applied to protect adult subjects with impaired decision-making capacity?

3c. If additional regulations are needed would a risk-based model, such as a model based on the subpart D regulations be appropriate? If not, what type of regulatory model would be appropriate?

3d. If additional regulations are needed, would it be appropriate to develop additional regulations that would only apply to a subset of the population of adult subjects with impaired decision-making capacity? For example, would it be appropriate to develop additional regulations that would apply only to adult individuals who have no capacity to provide legally effective informed consent (e.g.

comatose individuals or individuals in a persistent vegetative state)?

4. How should the population of adults with impaired decision-making be defined for the purposes of guidance or regulation? Note that the subpart D regulations contain a definition of the term "children," who are defined as " \* \* \* persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." See 45 CFR 46.402(a). Does the definition of the term "children" in the subpart D regulations provide a helpful model for developing a definition of "adults with impaired decision-making capacity," or would a definition modeled on the definition of "children" inappropriately exclude adult individuals who are at risk of decisional impairment, and those who suffer from some form of persistent, fluctuating, or progressive decisional impairment, but who nevertheless retain the capacity to give legally effective informed consent under the applicable law of the jurisdiction in which the research will be conducted? If a comparable definition of adults with impaired decision-making capacity was to be developed, such a definition could read: "Adults with impaired decision-making capacity are persons who do not have the capacity to give legally effective informed consent to treatments or procedures involved in research/clinical investigation, under the applicable law of the jurisdiction in which the research/clinical investigation will be conducted."

5. In some circumstances, certain adult subjects may develop impaired decision-making capacity (e.g. persistent, fluctuating, or progressive decisional impairment) after consenting and enrolling in research. In such cases, is guidance needed, or are additional regulations necessary, in order to adequately protect adult subjects who become decisionally impaired during their participation in research? For example, should guidance or additional regulations address when it would be appropriate for investigators to seek the consent of the subject's legally authorized representative to enable the subject's continued participation?

6. If guidance or additional regulations are needed to adequately protect the rights and welfare of subjects with impaired decision-making capacity, should such guidance or regulations address the issue of assent? Note that the subpart D regulations generally require that IRBs determine that adequate provisions are made for soliciting the assent of children when in

the judgment of the IRB the children are capable of providing assent. (See 45 CFR 46.408.)

6a. If an adult with impaired decision-making capacity is capable of providing assent to participation in research, should the guidance or regulation indicate that the adult subject's assent should always be a condition for proceeding with the research? If there are circumstances when an adult subject's assent should not be necessary, what are those circumstances?

**Melody Lin,**

*Deputy Director, Office for Human Research Protections.*

[FR Doc. E7-17490 Filed 9-4-07; 8:45 am]

**BILLING CODE 4150-36-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): National HIV Behavioral Surveillance System, Funding Opportunity Announcement (FOA) Number PS 08-001**

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 aforementioned meeting.

*Time and Date:*

8:30 a.m.-5 p.m., October 22, 2007

(Closed).

8 a.m.-2 p.m., October 23, 2007 (Closed).

*Place:* Sheraton Gateway Atlanta Airport Hotel, 1900 Sullivan Road, Atlanta, Georgia 30337, Telephone (770) 997-1100.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters to be Discussed:* The meeting will include the review, discussion, and evaluation of "National HIV Behavioral Surveillance System," FOA Number PS 07-001.

*Contact Person for More Information:*

Shoukat Qari, D.V.M., Ph.D., Scientific Review Administrator, Strategic Science and Program Unit, Office of the Director, Coordinating Center for Infectious Diseases, CDC, 1600 Clifton Road, NE., MS E05,

Atlanta, GA 30333, Telephone (404) 639-6101.

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: August 29, 2007.

**Diane C. Allen,**

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

[FR Doc. E7-17519 Filed 9-4-07; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**National Center for Environmental Health/Agency for Toxic Substances and Disease Registry; the Program Peer Review Subcommittee (PPRS) of the Board of Scientific Counselors (BSC), Centers for Disease Control and Prevention (CDC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR): Teleconference**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), CDC, NCEH/ATSDR announces the aforementioned subcommittee meeting:

*Time and Date:* 3 p.m.-5 p.m., September 24, 2007.

*Place:* The teleconference will originate at NCEH/ATSDR in Atlanta, Georgia. To participate, dial (877)315-6535 and enter conference code 383520.

*Purpose:* Under the charge of the BSC, NCEH/ATSDR, the PPRS will provide the BSC, NCEH/ATSDR with advice and recommendations on NCEH/ATSDR program peer review. They will serve the function of organizing, facilitating, and providing a long-term perspective to the conduct of NCEH/ATSDR program peer review.

*Matters To Be Discussed:* A discussion of Preparedness and Emergency Response Peer Review, and review and approve previous meeting minutes.

Agenda items are subject to change as priorities dictate.

*Supplementary Information:* This meeting is scheduled to begin at 3 p.m. Eastern Time. To participate, please dial (877)315-6535 and enter conference code 383520. Public comment period is scheduled for 4-4:15 p.m.

*Contact Person for More Information:* Sandra Malcom, Committee Management Specialist, Office of Science, NCEH/ATSDR, M/S E-28, 1600 Clifton Road, NE., Atlanta, Georgia 30333, Telephone (404)498-0622.

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 NCEH/ATSDR.

Dated: August 29, 2007.

**Diane C. Allen,**

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

[FR Doc. E7-17522 Filed 9-4-07; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request; Proposed Projects**

*Title:* Child Care and Development Fund Tribal Annual Report (ACF-700 Report).

*OMB No.:* 0980-0241.

*Description:* The Child Care and Development Fund (CCDF) report requests annual Tribal aggregate information on services provided through the CCDF, which is required by the CCDF Final Rule (45 CFR parts 98 and 99). Tribal Lead Agencies (TLAs) are required to submit annual aggregate data appropriate to Tribal programs on children and families receiving CCDF-funded child care services.

The CCDF statute and regulations also require TLAs to submit a supplemental narrative as part of the ACF-700 report. This narrative describes general child care activities and actions in the TLA's service area and is not restricted to CCDF-funded child care activities. Instead, this description is intended to address all child care available in the TLA's service area. The ACF-700 and supplemental narrative report will be included in the Secretary's report to Congress, as appropriate, and will be shared with all TLA's to inform them of CCDF-funded activities in other Tribal programs.

*Respondents:* Tribal Governments.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-700 Report .....	260	1	38	9,880