

“Custodian”), with Medicare and Medicaid records pertaining to eligibility, claims, and billing which the Custodian will match in order to merge the information into a single database. Utilizing fraud detection software, the information will then be used to identify patterns of aberrant practices requiring further investigation. The following are examples of the type of aberrant practices that may constitute F&A by practitioners, providers, and suppliers in the State of Texas expected to be identified in this matching program: (1) billing for provisions of more than 24 hours of services in one day, (2) providing treatment and services in ways more statistically significant than similar practitioner groups, and (3) up-coding and billing for services more expensive than those actually performed.

**DESCRIPTION OF RECORDS TO BE USED IN THE MATCHING PROGRAM:**

The release of the data for CMS are maintained in the following SOR: National Claims History (NCH), System No. 09-70-0005 was most recently published in the **Federal Register**, at 67 FR 57015 (September 6, 2002). NCH contains records needed to facilitate obtaining Medicare utilization review data that can be used to study the operation and effectiveness of the Medicare program. Matched data will be released to HHSC pursuant to the routine use as set forth in the system notice.

Carrier Medicare Claims Record, System No. 09-70-0501 published in the **Federal Register** at 67 FR 54428 (August 22, 2002). Matched data will be released to HHSC pursuant to the routine use as set forth in the system notice.

Enrollment Database, System No. 09-70-0502 (formerly known as the Health Insurance Master Record) published at 67 FR 3203 (January 23, 2002). Matched data will be released to HHSC pursuant to the routine use set forth in the system notice.

Intermediary Medicare Claims Record, System No. 09-70-0503 published in the **Federal Register** at 67 FR 65982 (October 29, 2002). Matched data will be released to HHSC pursuant to the routine use as set forth in the system notice.

Unique Physician/Provider Identification Number (formerly known as the Medicare Physician Identification and Eligibility System), System No. 09-70-0525, was most recently published in the **Federal Register** at 53 FR 50584 (Dec 16, 1988). Matched data will be released to HHSC pursuant to the

routine use as set forth in the system notice.

Medicare Supplier Identification File, System No. 09-70-0530 was most recently published in the **Federal Register**, at 67 FR 48184 (July 23, 2002). Matched data will be released to HHSC pursuant to the routine use as set forth in the system notice.

Medicare Beneficiary Database, System No. 09-70-0536 published in the **Federal Register** at 67 FR 63392 (December 6, 2001). Matched data will be released to HHSC pursuant to the routine use as set forth in the system notice.

The data for HHSC are maintained in the following data files: The data that the Texas Medicaid Fraud and Abuse Detection System (MFADS) receives from the acute care claims processor comprises over 320 files. These files include not only the claims data, but also all other data necessary to process the claim such as client, provider, and reference information. The Texas Medicaid claims administrator vendor utilizes a real-time transaction processing system to adjudicate the claims and therefore, has organized the data to facilitate efficient transaction processing. This data organization results in the data being parsed out over a number of data tables. It is these data tables that are extracted for processing by the MFADS. As these files are received, they are organized or reassembled into an Oracle relational database to support access using the MFADS tools.

In addition to the organization of the data, there are numerous updates that take place during the monthly load process. The monthly acute extracts that are received contain data that has finalized during the month. Therefore, these files must be applied to the multi-year database, changing some of the data through an update process as well as adding additional records. It is due to these reasons that the data will be extracted from the MFADS database rather than from incoming data sources. All or part of these elements may be used in this data-matching program.

**INCLUSIVE DATES OF THE MATCH:**

The CMP shall become effective no sooner than 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, which ever is later. The matching program will continue for 18 months from the effective date and may be

extended for an additional 12 months thereafter, if certain conditions are met.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**American Indian-Alaska Native Head Start-University Partnerships Program**

*Federal Agency Contact Name:* Administration for Children and Families (ACF) & Office of Planning, Research and Evaluation (OPRE).

*Funding Opportunity Title:* American Indian-Alaska Native Head Start-University Partnerships.

*Announcement Type:* Initial.

*Funding Opportunity Number:* HHS-2004-ACF-OPRE-YF-0002.

*CFDA Number:* 93.600.

*Due Date for Letter of Intent (Encouraged):* 3 weeks prior to June 7, 2004.

*Due Date for Applications (Required):* The due date for the receipt of applications is June 7, 2004.

**I. Funding Opportunity Description**

Funds are provided for American Indian-Alaska Native Head Start-University Partnerships to build model research partnerships between American Indian-Alaska Native program staff, members of tribal communities, and researchers.

This grant program is part of a larger Head Start research effort. Three other grant funding mechanisms are being offered concurrently with the one described in this announcement. They include: (1) Head Start-University Partnerships: Measurement Development for Head Start Children and Families, (2) Head Start Graduate Student Research Grants, and (3) Head Start Graduate Student Research Partnership Development Grants. For more information, please see these other Head Start Research announcements listed in the **Federal Register** or listed on <http://www.Grants.Gov>, or send an inquiry to the email address listed above.

*Priority Area:* American Indian-Alaska Native Head Start-University Partnerships.

**A. Purpose**

This new initiative creates an opportunity for building model research partnerships between American Indian—Alaska Native program staff, members of tribal communities, and

researchers based in universities and other nonprofit research institutions. Research partnerships are intended to expand on the strengths of the researchers and grantee partners who constitute the partnerships in order to benefit the larger Head Start and early childhood community. Grantees are experts on the available strengths and needs of their families and communities, as well as the particular histories of their programs, and are expected to be valuable partners in developing research goals and questions. Grantees can usually benefit from technical expertise of researchers in all aspects of the initiative, from selection of assessment tools appropriate for their curriculum, methods for administering assessments, methods for measuring classroom quality, approaches for data entry and management, techniques for data analysis, and training of staff who will be responsible for each phase. Such partnerships necessitate that researchers become familiar with the goals, approaches, and existing systems. They also require that the technical experts encourage professional development of program personnel to become increasingly adept at managing research and evaluation on their own. The successful partnership will be able to provide evidence that the research project is developing information to improve the early learning environments for American Indian—Alaska Native Head Start children.

The lessons learned from model partnerships can then be disseminated through training and technical assistance, both through the Head Start network and by other means. Examples of products expected from these partnerships include, but are not limited to: Methodological approaches for sampling, assessment and analysis at the local program level; plans for reporting data to teachers, parents, and management staff; data management systems; integrated curricular and assessment approaches; professional development approaches including coursework and training materials; and plans for disseminating information to the broader Head Start and child development communities.

#### *B. Statutory Authority*

Section 649 of the Head Start Act, as amended by the Coats Human Services Reauthorization Act of 1998 (Pub.L. 105–285) and 42 U.S.C. 9844.

#### *C. Background*

The American Indian-Alaska Native Program Branch funds Head Start and Early Head Start programs operated by

tribes, consortia, and/or corporations. The majority of grantees serve and reside on tribal reservations. Generally, grants are awarded to tribal governments, with tribal presidents, governors, executive directors or administrators as authorizing officials.

American Indian and Alaska Native (AI–AN) Head Start programs reflect the diversity of languages and traditions that exist in AI–AN cultures. Substantial numbers of children served by the AI–AN Branch speak an American Indian language or language other than English or Spanish as their dominant language. The programs vary greatly in size, with the smallest grantee serving about 15 children and the largest, more than 4,000 children and families. The programs also are geographically diverse, and are located in isolated rural settings as well as in urban areas. AI–AN grantees provide comprehensive services to children and families through center and home-based options, as well as combinations and locally designed configurations.

Because legislative mandates have specifically excluded tribal programs from national Head Start research and evaluation activities (Head Start Authorization Act, October 27, 1998, Section 649(g)(4)), current national research and evaluation activities of Head Start, such as the Family and Child Experiences Survey (FACES) and the Head Start Impact Study, exclude tribal programs from the population eligible for inclusion in the samples. The unique values, attitudes, and characteristics of the many different tribes create methodological challenges for inclusion in nationally representative samples for evaluation research.

At the same time, there are legislative provisions that require the study of Head Start programs for American Indian and Alaska Native children. Tribal Head Start programs have the same performance standards and requirements for assessing program outcomes as other Head Start programs. There is little prior research evidence available, however, to provide guidance about effective instructional, service delivery, or assessment approaches in tribal settings.

American Indian and Alaska Native Head Start programs need to be included in Head Start Bureau efforts to enhance the quality of Head Start programming, and to improve accountability by strengthening screening and assessment of child outcomes and program monitoring. There is a need, however, to increase the evidence base to provide direction for program enhancements, and such

activities must be conducted in a manner that takes into account the unique cultural values of tribes implementing Head Start programs.

For historical and ethical reasons tribal communities must have a significant voice in how research is designed and conducted in those settings. To support the development and implementation of research within and by tribal communities, ACF undertook in FY2002 an effort to document the existing knowledge base concerning early childhood programming and assessment in tribal settings, and to collect information on the research needs and priorities of tribal Head Start programs. Little was known about what research was currently being conducted by tribal Head Start programs, what the experiences of tribal programs in research partnerships with colleges and universities had been, and how ACF might support these partnerships. The project resulted in a review and synthesis of available research literature, both published and unpublished, that pertained to young children and families in American Indian and Alaska Native populations. That report is available online at: [http://www.acf.dhhs.gov/programs/core/ongoing\\_research/hs/hs\\_aian\\_report.html](http://www.acf.dhhs.gov/programs/core/ongoing_research/hs/hs_aian_report.html).

A second part of this effort was to conduct a series of visits to tribes to assess their own views about the following questions: (1) What kind of research is needed and desired in tribal Head Start settings; (2) what outcomes are important for American Indian and Alaska Native Head Start; (3) what programmatic and service delivery issues need to be studied; and (4) what are the issues in conducting research among American Indian and Alaska Native populations? Visits were arranged with 19 tribes to conduct “listening sessions” with tribal leadership, Head Start personnel, Head Start family members, and other community stakeholders. Other sessions were held in conjunction with national meetings of American Indian—Alaska Native Head Start grantees and technical assistance staff.

These efforts have documented the paucity of existing research that directly informs early childhood programming for American Indian and Alaska Native children and families. Few studies have taken into account the unique cultural and linguistic characteristics of the AI–AN population, and existing studies tend to be small, methodologically weak, and of limited generalizability to other settings. There is a need to develop the capacity for research in

tribal settings; research projects rarely are initiated by tribal members themselves, and the number of qualified individuals who have the ability to effectively partner with tribes to implement research is thought to be quite limited. At the same time, there is widespread recognition of the need for culturally relevant research, as well as substantial support among tribal members for research that will advance the knowledge base and improve the lives of the children and families who are served by Head Start in their communities.

Tribal communities have affirmed that they must have a significant voice in how the research is designed and conducted among their members. Cultural issues must be addressed in the development of methodologies, study procedures, and data collection instruments for use in conducting research among tribal Head Start programs. Differences among American Indian/Alaskan Native groups must be acknowledged and respected in developing the methodology and conducting the research. In addition to Head Start personnel, tribal leaders and community elders often must be part of the process in designing and conducting research in tribal settings.

The participants in the listening sessions identified a number of topics of interest to tribes, including:

- Identifying and addressing the unique characteristics and needs of American Indian and Alaska Native Head Start children and families that may affect learning; documenting and addressing cultural diversity within tribal Head Start settings;
- The role of Head Start in promoting and maintaining native languages and culture;
- Outcomes for bilingual children vs. English-only speakers;
- Long-term outcomes for AI-AN Head Start children, including studies of factors that promote or inhibit the successful transition to school and studies that compare outcomes for AI-AN Head Start children with those for other Head Start children;
- Comparisons of tribal Head Start children to non-tribal children;
- Effectiveness of instructional practices, tailored to the unique characteristics of tribal children, that promote school readiness;
- Availability of resources to meet unique tribal needs;
- Programs aimed at health and development, including health delivery models as well as preventive programs for adverse health and mental health outcomes;

- Staff development issues, including wage and benefit comparability between AI-AN and non-tribal early childhood educators, causes of staff turnover, ways to retain staff, identification of staff members' academic and non-academic skills that best promote child development within a cultural context, and providing staff development opportunities in geographically isolated communities;

- Development and utilization of culturally appropriate screening, assessment, and outcome measures;
- Methods for enhancing communication and cooperation among Head Start personnel, parents, tribal governments, and school district personnel;
- Identification of special needs among AI-AN Head Start children, and programs for addressing them;
- Effectiveness of methods for enhancing parent involvement, including promotion of knowledge about child development among parents, promotion of adult literacy, and promotion of father involvement;
- Impact of adverse conditions on child development, including geographic isolation and poverty, adverse family circumstances such as domestic violence or substance abuse, and historical experiences of racism, discrimination, and organized efforts aimed at the destruction of AI-AN culture.

Building on the needs identified both by participants in the Listening Sessions and by other consultants, this announcement will support research activities that are designed to promote partnerships between the research community and tribal communities that will support the development of young children and families in American Indian and Alaska Native Head Start and Early Head Start programs. Each partnership team of one or more AI-AN grantees and a research organization will identify or further develop a particular, self-selected research approach targeted toward better describing the unique characteristics and developmental needs of AI-AN children, evaluating or enhancing program practices, and/or developing approaches to outcomes assessment, based on the needs of the population served. The successful partnership will address topics that are decided through consultation among the researchers, AI-AN staff, and other tribal stakeholders, and that clearly reflect the interests of the AI-AN Head Start program.

## II. Award Information

*Funding Instrument Type:* Grant.

*Anticipated Total Program Funding:* \$1,000,000.

*Anticipated Number of Awards:* ACF anticipates funding 4-6 projects.

*Ceiling on Amount of Individual Awards:*

The Federal share of project costs shall not exceed \$200,000 for the first 12-month budget period inclusive of indirect costs and shall not exceed \$200,000 per year for the second through third 12-month budget periods.

An application that exceeds the upper value of the dollar range specified will be considered "non-responsive" and be returned to the applicant without further review.

*Floor of Individual Award Amounts:* None specified.

*Average Projected Award Amount:* None specified.

*Project Periods for Awards:* Project periods will be up to three years. Initial awards will be for the first one-year budget period. Requests for a second and/or third year of funding within the project period should be identified in the current application (on SF-424A), but such requests will be considered in subsequent years on a noncompetitive basis, subject to the applicant's eligibility status, the availability of funds, satisfactory progress of the grantee, and a determination that continued funding would be in the best interest of the Government.

## III. Eligibility Information

1. Eligible applicants include the following:

- State controlled institutions of higher education
- Private institutions of higher education
- Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
- Other: Faith-based and community organizations that meet all other eligibility requirements

### *Additional Information on Eligibility*

A. Eligible applicants are universities, four-year colleges, and not-for profit institutions on behalf of researchers who hold a doctorate degree or equivalent in their respective fields. The Principal Investigator must conduct research as a primary professional responsibility, and have published or have been accepted for publication in the major peer-reviewed research journals in the field as a first author or second author.

B. An important element of this announcement is the requirement that researchers demonstrate a partnership or partnerships with Head Start or Early Head Start programs as part of all

research efforts, including the development, piloting, refinement, training, and use of measures. The application must contain a letter from the Head Start or Early Head Start program certifying that they have entered into a partnership with the applicant and the application has been reviewed and approved by the Head Start Policy Council (see *Section IV. Application and Submission Information* for further details about these letters).

C. The Principal Investigator must agree to attend two meetings each year. The first is an annual grantee meeting which is typically scheduled during the summer or fall of each year and is held in Washington, DC. The second meeting each year alternates between the biennial Head Start National Research Conference in Washington, DC (June 28 to July 1, 2004) and the biennial meeting of the Society for Research in Child Development-SRCD (April, 2005). The budget should reflect travel funds for such purposes.

D. Faith-based and community organizations that meet all other eligibility criteria are eligible to apply.

E. Any nonprofit organization submitting an application must submit proof of its nonprofit status at the time of submission. Any of the following constitutes proof of nonprofit status:

- A copy of the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in Section 501(c)(3) of the IRS Code.
- A copy of a currently valid IRS tax exemption certificate.
- A written statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status.
- Any of the items above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local nonprofit affiliate.

F. Private, nonprofit organizations are encouraged to submit with their applications the survey located under "Grant Related Documents and Forms" titled "Survey for Private, Nonprofit Grant Applicants" at <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

#### 2. Cost Sharing or Matching.

There is no matching requirement.

#### 3. Other.

All applicants must have Dun & Bradstreet numbers. On June 27, 2003 the Office of Management and Budget published in the **Federal Register** a new Federal policy applicable to all Federal grant applicants. The policy requires all Federal grant applicants to provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements on or after October 1, 2003. The DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal (<http://www.Grants.gov>). A DUNS number will be required for every application for a new award or renewal/continuation of an award, including applications or plans under formula, entitlement, and block grant programs, submitted on or after October 1, 2003.

Please ensure that your organization has a DUNS number. You may acquire a DUNS number at no cost by calling the dedicated toll-free DUNS number request line on 1-866-705-5711 or you may request a number on-line at <http://www.dnb.com>.

Applications that fail to follow the required format described in *Section IV.2. Content and Form of Application Submission* will be considered non-responsive and will not be eligible for funding under this announcement.

Applications that exceed the \$200,000 ceiling will be considered non-responsive and will not be eligible for funding under this announcement.

### IV. Application and Submission Information

#### 1. Address To Request Application Package

The Head Start Research Support Technical Assistance Team, 1 (877) 663-0250, is available to answer questions regarding application requirements and to refer you to the appropriate contact person in ACF for programmatic questions. You may also email your questions to: [opre@xtria.com](mailto:opre@xtria.com). Refer to the Funding Opportunity Number: HHS-2004-ACF-OPRE-YF-0002. ACYF Operations Center/OPRE Grant Review Team/Xtria, LLC, c/o The Dixon Group, Inc., 118 Q Street, NE., Washington, DC 20002-2132, Attention: American Indian-Alaska Native Head Start-University Partnerships, 1 (877) 663-0250, E-mail [opre@xtria.com](mailto:opre@xtria.com).

*URL to Obtain an Application:* Copies of this Program Announcement may be downloaded approximately 5 days after publication in the **Federal Register** at <http://www.acf.dhhs.gov/programs/>

*core/ongoing\_research/funding/funding.html*. Application materials described in *Section IV.* can be downloaded from the following web site: <http://www.acf.hhs.gov/programs/ofs/forms.htm#apps>.

#### 2. Content and Form of Application Submission

An original and two copies of the complete application are required. The original copy must include all required forms, certifications, assurances, and appendices, be signed by an authorized representative, have original signatures, and be submitted unbound. The two additional copies of the complete application must include all required forms, certifications, assurances, and appendices and must also be submitted unbound. Applicants have the option of omitting from the application copies (not the original) specific salary rates or amounts for individuals specified in the application budget and Social Security Numbers, if otherwise required for individuals. The copies may include summary salary information.

*Format and Organization.* Applicants are strongly encouraged to limit their application to 100 pages, double-spaced, with standard one-inch margins and 12 point fonts. This page limit applies to both narrative text and supporting materials but not the Standard Federal Forms (see list below). Applicants must number the pages of their application beginning with the Table of Contents.

Applicants are advised to include all required forms and materials and to organize these materials according to the format, and in the order, presented below:

- a. Cover Letter
- b. Contact information sheet (see details below)
- c. Standard Federal Forms
  - Standard Application for Federal Assistance (form 424) Budget Information—Non-construction Programs (424A) Certifications Regarding Lobbying Disclosures of Lobbying Activities (if necessary) Certification Regarding Environmental Tobacco Smoke Assurance Regarding Non-construction Programs (form 424B) Assurance Regarding Protection of Human Subjects
- d. Table of Contents
- e. Project Narrative Statement (see details below)
- f. Appendices
  - Proof of Nonprofit Status (see Section V.1.F) Letter(s) of agreement with Head Start program(s) (see details below) Letter(s) of agreement with Head Start Policy Council(s) (see details below) Curriculum Vitae for

**Principal Investigators**

You may submit your application to us in either electronic or paper format.

To submit an application electronically, please use the <http://www.Grants.gov> apply site. If you use Grants.gov, you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to us.

Please note the following if you plan to submit your application electronically via Grants.gov:

- Electronic submission is voluntary.
- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation. We strongly recommend that you do not wait until the application deadline date to begin the application process through Grants.gov.
- To use Grants.gov, you, as the applicant, must have a DUNS Number and register in the Central Contractor Registry (CCR). You should allow a minimum of five days to complete the CCR registration.
- You will not receive additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format.
- You may submit all documents electronically, including all information typically included on the SF 424 and all necessary assurances and certifications.
- Your application must comply with any page limitation requirements described in this program announcement.
- After you electronically submit your application, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number. ACF will retrieve your application from Grants.gov.
- We may request that you provide original signatures on forms at a later date.
- You may access the electronic application for this program on <http://www.Grants.gov>.
- You must search for the downloadable application package by the CFDA number.

Private non-profit organizations may voluntarily submit with their applications the survey located under

“Grant Related Documents and Forms” titled “Survey for Private, Nonprofit Grant Applicants” at <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

**Content of Contact Information Sheet:** The contact information sheet should include complete contact information, including addresses, phone and fax numbers, and e-mail addresses, for the Principal Investigator(s) and the institution’s grants/financial officer (person who signs the SF-424).

**Content of Project Narrative Statement:** The project narrative should be carefully developed in accordance with ACF’s research goals and agenda as described in the Purpose, Background, and Priorities of this funding opportunity, and the structure requirements listed in *Section V. Application Review Information*. Please see *Section V.1. Criteria* for instructions on preparing the project summary/abstract and the full project description.

**Content of Letters of Agreement:** For research conducted with Head Start, the application must contain (A) an original copy of a letter from the Head Start or Early Head Start program certifying that they have entered into a research partnership with the applicant and (B) a separate letter certifying that the application has been reviewed and approved by the local Head Start Program Policy Council. Certification of approval or pending approval by the Policy Council must be an original letter from the official representative of the Policy Council itself.

**3. Submission Dates and Times**

The closing time and date for receipt of applications is 4:30 p.m. (Eastern Time Zone) on June 7, 2004. Mailed or handcarried applications received after 4:30 p.m. on the closing date will be classified as late.

**Deadline:** Mailed applications shall be considered as meeting an announced deadline if they are received on or before the deadline time and date at the following address: ACYF Operations Center/OPRE Grant Review Team/Xtria, LLC, c/o Dixon Group, Inc., Attention: American Indian-Alaska Native Head Start-University Partnerships, 118 Q Street, NE., Washington, DC 20002-2132.

Applicants are responsible for mailing applications well in advance, when using all mail services, to ensure that

the applications are received on or before the deadline time and date.

Applications hand-carried by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 9 a.m. and 4:30 p.m. (EST), Monday through Friday (excluding Federal holidays) at the above address. Applicants are cautioned that express/overnight mail services do not always deliver as agreed. ACF cannot accommodate transmission of applications by fax.

**Late applications:** Applications which do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

**Extension of deadlines:** ACF may extend application deadlines when circumstances such as acts of God (floods, hurricanes, etc.) occur, when there are widespread disruptions of mails service, or in other rare cases. Determinations to extend or waive deadline requirements rest with the ACF Chief Grants Management Officer.

**Due Date for Letters of Intent (Encouraged):** 3 weeks prior to June 7, 2004. If you plan to submit an application, ACF requests you notify us by fax or e-mail at least three weeks prior to the submission deadline date. This information will be used only to determine the number of expert reviewers needed to review the applications. Include only the following information in this fax or email: the number and title of this announcement; the name, address, telephone and fax number, e-mail address of the Principal Investigator(s), the fiscal agent (if known); and the name of the university or nonprofit institution. Do not include a description of your proposed project. Send this information to “The Head Start Research Support Team” at—Fax: 1 (703) 821-3989 or E-mail: [opre@xtria.com](mailto:opre@xtria.com).

The table below provides additional detail about the standard Federal forms that need to be submitted, including what information is required on them, where these forms can be found, and when they must be submitted.

What to submit	Required content	Required form or format	When to submit
Standard Application for Federal Assistance (form SF 424).	Must be filled out completely, signed, and enclosed with application.	May be found at <a href="http://acf.hhs.gov/programs/ofs/forms.htm">http://acf.hhs.gov/programs/ofs/forms.htm</a> .	By application due date.

What to submit	Required content	Required form or format	When to submit
Budget Information—Non-construction Programs (form SF 424A).	Must be filled out completely and enclosed with application.	May be found at <a href="http://acf.hhs.gov/programs/ofs/forms.htm">http://acf.hhs.gov/programs/ofs/forms.htm</a> .	By application due date.
Certification Regarding Lobbying.	Must be signed and enclosed with application.	May be found at <a href="http://acf.hhs.gov/programs/ofs/forms.htm">http://acf.hhs.gov/programs/ofs/forms.htm</a> .	By application due date.
Disclosure of Lobbying Activities (SF LLL).	If necessary (see Certification Regarding Lobbying), must be filled out completely, signed, and enclosed with application.	May be found at <a href="http://acf.hhs.gov/programs/ofs/forms.htm">http://acf.hhs.gov/programs/ofs/forms.htm</a> .	By application due date.
Certification Regarding Environmental Tobacco Smoke.	Copy must be enclosed with application (signing and submitting the proposal certifies its content).	May be found at <a href="http://acf.hhs.gov/programs/ofs/forms.htm">http://acf.hhs.gov/programs/ofs/forms.htm</a> .	By application due date.
Assurance Regarding Non-construction Programs (form SF 424B).	Must be signed and enclosed with application.	May be found at <a href="http://acf.hhs.gov/programs/ofs/forms.htm">http://acf.hhs.gov/programs/ofs/forms.htm</a> .	By application due date.
Assurance Regarding Protection of Human Subjects.	Must be filled out completely, signed, and enclosed with application.	May be found at <a href="http://acf.hhs.gov/programs/ofs/forms.htm">http://acf.hhs.gov/programs/ofs/forms.htm</a> .	By application due date.

*Additional Forms:* Private non-profit organizations may voluntarily submit with their applications the survey located under “Grant Related Documents and Forms” titled “Survey for Private, Nonprofit Grant Applicants” at <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

What to submit	Required content	Required form or format	When to submit
Survey for Private, Non-Profit Grant Applicants.	Per required form .....	May be found at <a href="http://acf.hhs.gov/programs/ofs/forms.htm">http://acf.hhs.gov/programs/ofs/forms.htm</a> .	By application due date.

4. Intergovernmental Review

State Single Point of Contact (SPOC)

This program is covered under Executive Order 12372, “Intergovernmental Review of Federal Programs,” and 45 CFR Part 100, “Intergovernmental Review of Department of Health and Human Services Programs and Activities.” Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

All States and Territories except Alabama, Alaska, Arizona, Colorado, Connecticut, Hawaii, Idaho, Indiana, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, Wyoming, and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-six jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian Tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and

review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a. Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the “accommodation or explain” rule.

When comments are submitted directly to ACF, they should be addressed to: Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L’Enfant Promenade, Washington, DC 20447. A current list of the Single Points of Contact (SPOCs) for each State and Territory is posted at the following Web site: <http://www.whitehouse.gov/omb/grants/spoc.html>.

5. Funding Restrictions

- A. Pre-award costs are not allowable.
- B. The applicant is strongly encouraged to apply the University’s or nonprofit institution’s off-campus research rates for indirect costs.

6. Other Submission Requirements

*Electronic Address to Submit Applications:* <http://www.Grants.Gov>

*Electronic Submission:* Please see Section IV.2. Content and Form of Application Submission for guidelines and requirements when submitting applications electronically.

*Submission by Mail:* Mailed applications shall be considered as meeting an announced deadline if they are received on or before the deadline time and date at the following address: ACYF Operations Center/OPRE Grant Review Team/Xtria, LLC, c/o Dixon Group, Inc., Attention: American Indian-Alaska Native Head Start-University Partnerships, 118 Q Street, NE., Washington, DC 20002–2132.

Applicants are responsible for mailing applications well in advance, when using all mail services, to ensure that the applications are received on or before the deadline time and date.

*Hand Delivery:* Applications hand-carried by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 9 a.m. and 4:30 p.m. (EST), Monday through Friday (excluding Federal holidays) at the above address. Applicants are cautioned that express/overnight mail services do not always deliver as agreed. ACF cannot accommodate transmission of applications by fax.

*Due Date for Letters of Intent (Encouraged)*: 3 weeks prior to June 7, 2004. If you plan to submit an application, ACF requests you notify us by fax or e-mail at least three weeks prior to the submission deadline date. This information will be used only to determine the number of expert reviewers needed to review the applications. Include only the following information in this fax or email: the number and title of this announcement; the name, address, telephone and fax number, e-mail address of the Principal Investigator(s), the fiscal agent (if known); and the name of the university or nonprofit institution. Do not include a description of your proposed project. Send this information to "The Head Start Research Support Team" at—Fax: 1 (703) 821-3989 or E-mail: [opre@xtria.com](mailto:opre@xtria.com).

## V. Application Review Information

### 1. Criteria

The Paperwork Reduction Act of 1995 (Pub. L. 104-13): Public reporting burden for this collection of information is estimated to average 25 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection information. The project description is approved under OMB Control Number 0970-0139 which expires 3/31/2004. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

#### Purpose

The project description provides a major means by which an application is evaluated and ranked to compete with other applications for available assistance. The project description should be concise and complete and should address the activity for which Federal funds are being requested. Supporting documents should be included where they can present information clearly and succinctly. In preparing your project description, all information requested through each specific evaluation criteria should be provided. Awarding offices use this and other information in making their funding recommendations. It is important, therefore, that this information be included in the application.

#### General Instructions

ACF is particularly interested in specific factual information and statements of measurable goals in

quantitative terms. Project descriptions are evaluated on the basis of substance, not length. Extensive exhibits are not required. Cross-referencing should be used rather than repetition. Supporting information concerning activities that will not be directly funded by the grant or information that does not directly pertain to an integral part of the grant-funded activity should be placed in an appendix.

Pages should be numbered and a table of contents should be included for easy reference.

Applicants required to submit a full project description shall prepare the project description statement in accordance with the following instructions and the specified evaluation criteria. The instructions give a broad overview of what your project description should include while the evaluation criteria expands and clarifies more program-specific information that is needed.

*A. Project Summary/Abstract*: Provide a summary of the project description (one page or less) with reference to the funding request.

*B. Objectives and Need for Assistance*: Clearly identify the physical, economic, social, financial, institutional, and/or other problem(s) requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support from concerned parties other than the applicant, may be included. Any relevant data based on planning studies should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed. In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

*C. Results and Benefits Expected*: Identify the results and benefits to be derived. For example, explain how your proposed project will achieve the specific goals and objectives you have set; specify the number of children and families to be served, and how the services to be provided will be funded consistent with the local needs assessment. Or, explain how the expected results will benefit the population to be served in meeting its needs for early learning services and activities. What benefits will families derive from these services? How will the services help them? What lessons will

be learned which might help other agencies and organizations that are addressing the needs of a similar client population?

*D. Approach*: Outline a plan of action, which describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors which might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement.

Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of people to be served and the number of activities accomplished. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates.

If any data is to be collected, maintained, and/or disseminated, clearances may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any "collection of information that is conducted or sponsored by ACF."

List organizations, cooperating entities, consultants, or other key individuals who will work on the project along with a short description of the nature of their effort or contribution.

*E. Evaluation*: Provide a narrative addressing how the results of the project and the conduct of the project will be evaluated. In addressing the evaluation of results, state how you will determine the extent to which the project has achieved its stated objectives, and the extent to which the accomplishment of objectives can be attributed to the project. Discuss the criteria to be used to evaluate results, and explain the methodology that will be used to determine if the needs identified and discussed are being met, and if the project results and benefits are being achieved. With respect to the conduct of the project, define the procedures to be employed to determine whether the project is being conducted in a manner consistent with the work plan presented and discuss the impact of the project's various activities on the project's effectiveness.

*F. Additional Information*: Following are requests for additional information that need to be included in the application:

1. *Staff and Position Data:* Provide a biographical sketch for each key person appointed and a job description for each vacant key position. A biographical sketch will also be required for new key staff as appointed.

2. *Organizational Profiles:* Provide information on the applicant organizations(s) and cooperating partners such as organizational charts, financial statements, audit reports or statements from CPAs/Licensed Public Accountants, Employer Identification Numbers, names of bond carriers, contact persons and telephone numbers, child care licenses and other documentation of professional accreditation, information on compliance with Federal/State/local government standards, documentation of experience in the program area, and other pertinent information. Any nonprofit organization submitting an application must submit proof of its nonprofit status in its application at the time of submission.

The nonprofit agency can accomplish this by providing a copy of the applicant's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS code, or by providing a copy of the currently valid IRS tax exemption certificate; or by providing a copy of the articles of incorporation bearing the seal of the State in which the corporation or association is domiciled.

3. *Letters of Support:* Provide statements from the community, public and commercial leaders that support the project proposed for funding. All documents must be included in the application at the time of submission.

G. *Budget and Budget Justification:* Provide line item detail and detailed calculations for each budget object class identified in the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. The detailed budget must also include a breakout by the funding sources identified in Block 15 of the SF-424.

Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

*General:* The following are guidelines for preparing the budget and budget justification. Both Federal and non-Federal resources shall be detailed and justified in the budget and narrative justification. For purposes of preparing the budget and budget justification, "Federal resources" refers only to the

ACF grant for which you are applying. Non-Federal resources are all other Federal and non-Federal resources. It is suggested that budget amounts and computations be presented in a columnar format: first column, object class categories; second column, Federal budget; next column(s), non-Federal budget(s), and last column, total budget. The budget justification should be a narrative.

#### Personnel

*Description:* Costs of employee salaries and wages.

*Justification:* Identify the project director or Principal Investigator, if known. For each staff person, provide the title, time commitment to the project (in months), time commitment to the project (as a percentage or full-time equivalent), annual salary, grant salary, wage rates, etc. Do not include the costs of consultants or personnel costs of delegate agencies or of specific project(s) or businesses to be financed by the applicant.

#### Fringe Benefits

*Description:* Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

*Justification:* Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, FICA, retirement insurance, taxes, etc.

#### Travel

*Description:* Costs of project-related travel by employees of the applicant organization (does not include costs of consultant travel).

*Justification:* For each trip, show the total number of traveler(s), travel destination, duration of trip, per diem, mileage allowances, if privately owned vehicles will be used, and other transportation costs and subsistence allowances. Travel costs for key staff to attend ACF-sponsored workshops must be detailed in the budget.

#### Equipment

*Description:* "Equipment" means an article of nonexpendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals or exceeds the lesser of (a) the capitalization level established by the organization for the financial statement purposes, or (b) \$5,000. (**Note:** Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty,

protective in-transit insurance, freight, and installation shall be included in or excluded from acquisition cost in accordance with the organization's regular written accounting practices.)

*Justification:* For each type of equipment requested, provide a description of the equipment, the cost per unit, the number of units, the total cost, and a plan for use on the project, as well as use or disposal of the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy or section of its policy which includes the equipment definition.

#### Supplies

*Description:* Costs of all tangible personal property other than that included under the Equipment category.

*Justification:* Specify general categories of supplies and their costs. Show computations and provide other information, which supports the amount requested.

#### Contractual

*Description:* Costs of all contracts for services and goods except for those that belong under other categories such as equipment, supplies, construction, etc. Third party evaluation contracts (if applicable) and contracts with secondary recipient organizations, including delegate agencies and specific project(s) or businesses to be financed by the applicant, should be included under this category.

*Justification:* All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. Recipients and subrecipients, other than States that are required to use Part 92 procedures, must justify any anticipated procurement action that is expected to be awarded without competition and exceed the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently set at \$100,000). Recipients might be required to make available to ACF pre-award review and procurement documents, such as request for proposals or invitations for bids, independent cost estimates, etc.

**Note:** Whenever the applicant intends to delegate part of the project to another agency, the applicant must provide a detailed budget and budget narrative for each delegate agency, by agency title, along with the required supporting information referred to in these instructions.

#### Other

*Description:* Enter the total of all other costs. Such costs, where applicable and

appropriate, may include but are not limited to insurance, food, medical and dental costs (noncontractual), professional services costs, space and equipment rentals, printing and publication, computer use, training costs, such as tuition and stipends, staff development costs, and administrative costs.

*Justification:* Provide computations, a narrative description, and a justification for each cost under this category.

#### Indirect Charges

*Description:* Total amount of indirect costs. This category should be used only when the applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency.

*Justification:* An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. If the applicant organization is in the process of initially developing or renegotiating a rate, it should immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. It should be noted that when an indirect cost rate is requested, those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

#### Non-Federal Resources

*Description:* Amounts of non-Federal resources that will be used to support the project as identified in Block 15 of the SF-424.

*Justification:* The firm commitment of these resources must be documented and submitted with the application in order to be given credit in the review process. A detailed budget must be prepared for each funding source.

#### Evaluation Criteria

*Competitive Criteria for Reviewers:* American Indian-Alaska Native Head Start-University Partnerships—The three criteria areas that follow will be used to review and evaluate each application. Address each in the Project

Narrative Section of the application. The point values indicate the maximum numerical weight each criterion will be awarded in the review process. (100 points total).

*Approach:* 45 points.

- The extent to which the proposal provides evidence that the research plan has been jointly developed by the research institution and the Head Start program, as well as other relevant tribal stakeholders;

- The extent to which the research plan is adequately described and meets the goal of supporting the development of children in American Indian and Alaska Native Head Start.

- The extent to which the proposal is responsive to the questions outlined in the "additional requirements" section

- The extent to which the research design is appropriate and sufficient for addressing the questions of the study

- The extent to which the planned research specifies the measures to be used, their psychometric properties, and the analyses to be conducted.

- The extent to which the planned procedures and measures are appropriate and sufficient for the questions of the study and the cultural contexts of the population to be studied.

- The extent to which the planned measures and analyses both reflect knowledge and use of state-of-the-art measures and analytic techniques and/or advance the state of the art.

- The extent to which the analytic techniques are appropriate for the question under consideration.

- The extent to which the proposed sample size is sufficient for the study.

- The extent to which the planned approach includes techniques for successful documentation and dissemination.

- The extent to which the budget and budget justification are appropriate for carrying out the proposed project.

*Staff and Position Data:* 35 points.

- The extent to which the Principal Investigator and other key research staff possess the research expertise necessary to implement the intervention and conduct the evaluation as demonstrated in the application and information contained in their vitae. It is expected that the Principal Investigator(s) has earned a doctorate or equivalent in the relevant field and has first or second author publications in major research journals.

- The extent to which the proposed staff reflect an understanding of and sensitivity to the issues of working in a tribal community setting and in partnership with American Indian—Alaska Native Head Start program staff and parents.

- The adequacy of the time devoted to this project by the Principal Investigator and other key staff in order to ensure a high level of professional input and attention.

- The extent to which the research plan offers opportunities for American Indian and Alaska Native personnel to be engaged or employed in the research activities, as appropriate.

*Results or Benefits Expected:* 20 points.

- The extent to which research questions are clearly stated.

- The extent to which the proposed research project is justified as meeting the needs of American Indian and Alaska Native children and families.

- The extent to which the research study makes a significant contribution to the knowledge base about supporting the early development of American Indian and Alaska Native children and their families.

- The extent to which the literature review is current and comprehensive and justifies the research to be conducted.

- The extent to which the questions that will be addressed or the hypotheses that will be tested are sufficient for meeting the stated objectives.

- The extent to which the proposal contains a dissemination plan that encompasses both professional and practitioner-oriented products, and meets the needs of the Head Start and/or community partner.

- The extent to which the questions are of importance and relevance for AI-AN children's development and welfare.

#### 2. Review and Selection Process

Each application will undergo an eligibility and conformance review by Federal staff. Applications that pass the eligibility and conformance review will be evaluated on a competitive basis according to the specified evaluation criteria.

The competitive review will be conducted in the Washington, DC metropolitan area by panels of Federal and non-Federal experts knowledgeable in the areas of early childhood education and intervention research, early learning, child care, and other relevant program areas.

Application review panels will assign a score to each application and identify its strengths and weaknesses.

OPRE will conduct an administrative review of the applications and results of the competitive review panels and make recommendations for funding to the Director of OPRE.

The Director of OPRE, in consultation with the Commissioner of the Administration on Children, Youth, and

Families (ACYF), will make the final selection of the applications to be funded. Applications may be funded in whole or in part depending on: (1) The ranked order of applicants resulting from the competitive review; (2) staff review and consultations; (3) the combination of projects that best meets the Bureau's objectives; (4) the funds available; and (5) other relevant considerations. The Director may also elect not to fund any applicants with known management, fiscal, reporting, program, or other problems, which make it unlikely that they would be able to provide effective services.

## VI. Award Administration Information

### 1. Award Notices

Successful applicants will be notified through the issuance of a Financial Assistance Award notice that sets forth the amount of funds granted, the terms and conditions of the grant award, the effective date of the award, the budget period for which initial support is given, and the total project period for which support is provided. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail. Organizations whose applications will not be funded will be notified in writing by ACF.

### 2. Administrative and National Policy Requirements

All applicants are responsible for conforming to the United States Executive Branch Code of Federal Regulations (<http://www.gpoaccess.gov/cfr/index.html>). The following regulations have been identified as having particular relevance for ACF grants: 45 CFR Parts 74 and 92.

### 3. Reporting Requirements

Programmatic Reports: Semi-annually and a final report is due 90 days after the end of the grant period.

Financial Reports: (SF-269 long form) Semi-annually and a final report is due 90 days after the end of the grant period.

Original reports and one copy should be mailed to: Administration for Children and Families, Office of Grants Management, Division of Discretionary Grants 370 L'Enfant Promenade, SW., Washington, DC 20447.

## VII. Agency Contacts

1. Program Office Contact ACYF Operations Center/OPRE Grant Review Team/Xtria, LLC, c/o The Dixon Group, Inc., 118 Q Street, NE., Washington, DC 20002-2132, Attention: American Indian-Alaska Native Head Start-University Partnerships, 1 (877) 663-0250, E-mail [opre@xtria.com](mailto:opre@xtria.com).

2. Grants Management Office Contact, Sylvia Johnson, ACF Division of Discretionary Grants, 370 L'Enfant Promenade, Washington, DC 20447, 1 (202) 260-7622, E-mail: [sjohnson@acf.hhs.gov](mailto:sjohnson@acf.hhs.gov).

## VIII. Other Information

Applicants under this announcement are advised that subsequent sale and distribution of products developed under this grant will be subject to the Code of Federal Regulations, Title 45, Part 74 or Part 92.

The use of secondary data analysis in order to refine and validate newly-developed measures in relation to already standardized measures is strongly advised.

### Definitions

**Budget Period**—for the purposes of this announcement, budget period means the 12-month period of time for which ACF funds are made available to a particular grantee (e.g., beginning on September 16, 2004, and ending on September 15, 2005).

**Project Period**—for the purposes of this announcement, project period means the 36-month period starting by September 2004, and ending by September, 2007.

Dated: March 26, 2004.

### Naomi Goldstein,

Acting Director, Office of Planning, Research, and Evaluation.

[FR Doc. 04-7260 Filed 4-5-04; 8:45 am]

BILLING CODE 4184-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Science Board to the Food and Drug Administration; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

**Name of Committee:** Science Board to the Food and Drug Administration.

**General Function of the Committee:** To provide advice and recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on April 22, 2004, from 8 a.m. to 5 p.m.

**Location:** Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD.

**Contact Person:** Jan Johannessen, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687, or e-mail: [jjohannessen@oc.fda.gov](mailto:jjohannessen@oc.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** The Board will hear about and discuss FDA's Obesity Working Group report (<http://www.fda.gov/oc/initiatives/obesity/>) and the Critical Path white paper (<http://www.fda.gov/bbs/topics/news/2004/NEW01035.html>).

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 15, 2004. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 15, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jan Johannessen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 29, 2004.

### Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 04-7676 Filed 4-5-04; 8:45 am]

BILLING CODE 4160-01-S