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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[Program Announcement No. ACF/ACYF/HS-FY 2000-01]

### Fiscal Year 2000 Discretionary Announcement for Select Areas of Early Head Start; Availability of Funds and Request for Applications

**AGENCY:** Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), DHHS.

**ACTION:** Notice.

**SUMMARY:** The Administration on Children, Youth and Families announces financial assistance to be competitively awarded to local public and private entities—including Early Head Start and Head Start grantees—to provide child and family development services for low-income families with children under age three and pregnant women. Early Head Start programs provide early, continuous, intensive and comprehensive child development and family support services on a year-round basis to low-income families. The purpose of the Early Head Start program is to enhance children's physical, social, emotional, and intellectual development; to support parents' efforts to fulfill their parental roles; and to help parents move toward self-sufficiency.

The funds available will be competitively awarded to eligible applicants to operate Early Head Start programs in select service areas.

Grants will be competitively awarded to eligible applicants, including current Head Start and Early Head Start grantees, to operate Early Head Start programs in geographic areas currently served by existing Early Head Start grantees which were first funded in fiscal year 1995 (see list below for the geographic areas). In awarding these grants, ACYF is interested in assuring that communities currently served by these existing grantees will have an opportunity to continue receiving services to low-income families with infants and toddlers and pregnant women through Early Head Start. Applicants in each geographic area will

compete for funds against other applicants wishing to serve the same geographic area. There are 49 such competitive areas.

**DATES:** The closing date and time for receipt of applications is 5:00 p.m. EDT on November 23, 1999.

**FOR FURTHER INFORMATION CONTACT:** A copy of the program announcement and necessary application forms can be obtained by contacting: Early Head Start, ACYF Operations Center, 1815 North Fort Myer Drive, Suite 300, Arlington, Virginia 22209, The telephone number is 1-800-351-2293. Copies of the program announcement can be downloaded from the Head Start web site at: [www.acf.dhhs.gov/programs/hsb](http://www.acf.dhhs.gov/programs/hsb).

#### SUPPLEMENTARY INFORMATION:

#### Eligible Applicants

Applicants eligible to apply to become an Early Head Start program are local public and local non-profit and for-profit private entities. Local Early Head Start and Head Start grantees are eligible to apply.

#### Project Duration

The competitive awards made through this announcement will be for one-year budget periods and an indefinite project period. Subsequent year budget awards will be made non-competitively, subject to availability of funds and the continued satisfactory performance of the applicant.

#### Federal Share of Project Costs

Grantees that operate Early Head Start programs must, in most instances, provide a non-Federal contribution of at least 20 percent of the total approved costs of the project.

#### Available Funds

See the list below for the approximate amount of funds available for each geographic area.

#### Anticipated Number of Projects To Be Funded

It is estimated that there will be at least one award for each geographic area (49 geographic areas).

**Statutory Authority:** The Head Start Act, as amended, 42 U.S.C. 9831 *et seq.*

*Catalog of Federal Domestic Assistance:* Number 93.600, Head Start.

Dated: September 20, 1999.

**Patricia Montoya,**  
Commissioner, Administration on Children, Youth and Families.

#### Early Head Start Select Service Areas

The following are general descriptions of the service areas (geographic areas) to

be competed with approximated boundaries. The approximate funds available for each competition are indicated in parentheses.

#### Region I

1. Belknap County in New Hampshire (\$465,000)
2. Strafford County in New Hampshire (\$361,000)
3. Washington, Lamoille & Orange Counties in Vermont (\$658,000)

#### Region II

4. In Newark, New Jersey: Central Ward; West Ward; North Ward (Verona Avenue to Orange Street and Lake Street to McCarter Highway); and Bakery Village (\$1,022,000)
5. Warren and Sussex Counties in New Jersey (\$655,000)
6. Chautauqua County in New York (\$729,000)
7. Fort Greene in Brooklyn in New York (\$1,329,000)
8. Dutchess County in New York (\$795,000)
9. City of Syracuse and surrounding areas in New York (\$1,352,000)
10. Cantera in Municipality of San Juan; Cucharillas in Municipality of Catano; Las Flores in Municipality of Coamo; Brenas, Muachauchal and Santa Ana in Municipality of Vega Alta in Puerto Rico (\$1,384,000)
11. The Municipalities of Canovanas, Rio Grande, Loiza, Ceiba and Junco in Puerto Rico (\$2,514,000)

#### Region III

12. In Washington, DC: In Ward One an area bounded on the Northeast by Spring Road, on the Northwest by Piney Branch Parkway, on the East by Michigan Avenue and Florida Avenue, on the Southeast by S Street, and on the West by Rock Creek; in Ward Two an area bounded on the Northeast by New Jersey Avenue, Florida Avenue and S Street, on the Northwest by Florida Avenue, on the East by Florida Avenue and Southwest Freeway, on the Southeast by the Anacostia River, and on the West by the Potomac River; in Ward Four an area bounded on the Northeast by Eastern Avenue, on the Northwest by Western Avenue, on the Southeast by Michigan Avenue, and on the Southwest by Rock Creek; and in Ward Five an area bounded on the Northeast by Eastern Avenue, on the Northwest by South Dakota, on the Southeast by the Anacostia River, on the Southwest by Florida Avenue and on the West by Harewood Road (\$1,101,000)

13. In Southeast Baltimore, Maryland: An area bounded on the North by Monument Street, on the South by the Waterfront, on the East by the City Line and on the West by Broadway Street; Caroline County; and Southern Anne Arundel County, including the towns of Harwood, West River, Galesville, Lothian, Churchton, Deale, Shady Side and Traceys Landing (\$1,614,000)
14. Northern Montgomery County, including Gaithersburg and Germantown, in Maryland (\$706,000)
15. In North Philadelphia, Pennsylvania: an area bounded on the North by Allegheny Avenue, on the South by Norris Street, on the East by 5th Street and on the West by 17th Street, excluding the North Philadelphia Empowerment Zone area which is served by another EHS grantee (\$865,000)
16. Monagalia County in West Virginia (\$707,000)

*Region IV*

17. Grayson and Breckinridge Counties in Kentucky (\$593,000)
18. In Kentucky: The Counties of Calloway, Fulton, Marshall, Hickman, Ballard and Carlisle; the towns of Mayfield, Fancy Farm, Lowes, Sedalia, Symsonia and Wingo in Graves County; the towns of Bowling Green, Rockfield, Albatoon, Rich Panel, and Plano in Warren County; and the towns of Paducah, Concord, Farley, Heath, Hendron and Loneoak in McCracken County (\$1,114,000)
19. City of Asheville, and towns of Woodson, Emma and Johnstown in North Carolina (\$779,000)
20. In Greenville, South Carolina: The neighborhoods of Nicholstown (including the Jesse Jackson Town Homes), Woodland-Pierce Homes, and Parker District (including Monaghan, San Souci) (\$462,000)
21. Communities of Soddy-Daisy, and Cedar Hill in Hamilton County in Tennessee (\$581,000)
22. Counties of Henry, Weakley, and Gibson in Tennessee (\$982,000)
23. City of Homestead and towns of Brownsville, Scott Carver, Liberty City, Winwood, Goulds, Leisure City, Carol City and OpaLocka in Dade County in Florida (\$1,768,000)
24. Communities of Majestic Oaks, Sugarfoot Oaks, Tower Oaks, Cedar Ridge, Clayton Estates, Magnolia Plantation in Alachua County in Florida (\$715,000)

25. Chattooga County in Georgia (\$616,000)
26. City of Laurel and Towns of Ellisville and Soso in Jones County; Walnut Grove in Leake County; and Job Corps site in Crystal Springs in Copiah County in Mississippi (\$1,121,000)

*Region V*

27. Counties of Columbia, Adams, Dodge, Juneau and Sauk in Wisconsin (\$717,000)
28. Community area of Grand Boulevard in Chicago, Illinois (\$731,000)
29. In Chicago, Illinois, the community areas\* of: (\$2,126,000)
  - 29a. Oakland
  - 29b. Albany Park
  - 29c. North Lawndale
  - 29d. Gage Park
  - 29e. Fuller Park
  - 29f. Near West Side
  - 29g. Roseland
  - 29h. West Town
  - 29i. Austin
  - 29j. Logan Square
  - 29k. West Pullman
  - 29l. Chatham
  - 29m. Woodlawn
  - 29n. Washington Heights
  - 29o. Near North Side
  - 29p. Garfield Park
  - 29q. Douglas

\* Applicants may apply to serve one or more community areas in Chicago.

30. Counties of Edwards, Gallatin, Hamilton, Saline, Wabash, Wayne and White in Illinois. (\$1,035,000)
31. Vigo County in Indiana (\$646,000)
32. Clermont County in Ohio (\$729,000)
33. Communities of Over-the-Rhine and Mount Auburn in Central Cincinnati in Ohio (\$564,000)

*Region VI*

34. In Westside of San Antonio, Texas: An area bounded by Woodlawn on the North, U.S. Highway 90 on the South, by Interstate 35 on the East and by Callahan on the West (\$1,119,000)
35. In Dallas, Texas: The communities of Pleasant Grove (this community generally consists of an area bounded by I-635 on the North and East, I-45 on the South and I-30 on the West); and South Oak Cliff (this community generally consists of an area bounded by I-35 on the North, I-20 on the South, I-45 on the East and I-30 on the West) (\$978,000)
36. In San Antonio, Texas: In general, the communities of Fredericksburg II, Circle North, New Westwood, Terrell Plaza, Fort Sam and Mount Zion (\$1,215,000)

*Region VII*

37. Counties of Clay, Buena Vista, Dickinson, Emmet, O'Brien, Osceola, Pala Alto, and Pocahontas in Iowa (\$648,000)
38. In Southeast area of Wichita, Kansas: An area bounded by Murdock Street on the North, 47th South Street on the South, Woodlawn Street on the East and Main Street on the West (\$790,000)
39. Counties of Saline, Dickinson and Elsworth in Kansas (\$587,000)
40. Counties of Platte, Holt, Valley, Garfield, Sherman, Howard, Greeley, and Colfax in Nebraska (\$939,000)

*Region VIII*

41. School District 2 and 11 in El Paso County in Colorado (\$1,139,000)

*Region IX*

42. In Phoenix, Arizona: The area bounded by Camelback Road on the North, Elliot Road on the South, 40th Street on the East, and 43rd Avenue on the West (\$1,381,000)
43. In Humboldt County, California: The cities of Arcata, Eureka, Fortuna, Rio Dell, and McKinleyville and surrounding areas; and in Del Norte County the cities of Crescent City, Fort Dick and Smith River and surrounding areas (\$957,000)
44. In the city of Sacramento, California: The communities of Del Paso Heights, North Sacramento/Gardenland, Midtown, Oak Park, South Sacramento, Meadowview, Natomas, Land Park and Arden/Howe; and in Sacramento County the cities of Citrus Heights and Galt and the towns of Rio Linda/Everta, North Highlands, Foothill Farms, Orangevale, Carmichael, Fair Oaks, Rancho Cordova, South Sacramento, Franklin/Laguna, Elk Grove, and Antelope (\$2,537,000)

*Region X*

45. The villages of Pilot Station and St. Mary's in the Lower Yukon area and the villages of Nunapitchuk and Akiak in the Kuskokwin Delta area in Alaska (\$623,000)
46. The city of Medford and metropolitan area; and the Illinois Valley in Oregon (\$813,000)
47. The City of Spokane and surrounding areas in Washington (\$969,000)

*American Indian Programs*

48. Spirit Lake Reservation in Benson County in North Dakota (\$993,000)

49. Port Gamble S'Klallam Reservation in Kitsap County in Washington (\$285,000)

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 99D-3082]

#### International Conference on Harmonisation; Choice of Control Group in Clinical Trials

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a draft guidance entitled "E10 Choice of Control Group in Clinical Trials." The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance sets forth general principles that are relevant to all controlled trials and are especially pertinent to the major clinical trials intended to demonstrate drug (including biological drug) efficacy. The draft guidance describes the principal types of control groups and discusses their appropriateness in particular situations. The draft guidance is intended to assist sponsors and investigators in the choice of control groups for clinical trials.

**DATES:** Written comments by December 23, 1999.

**ADDRESSES:** Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the draft guidance are available from the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4573. Single copies of the guidance may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), or by calling the CBRE Voice Information System at 1-800-835-4709 or 301-827-1800. Copies may be obtained from CBRE's FAX Information System at 1-888-CBER-FAX or 301-827-3844.

**FOR FURTHER INFORMATION CONTACT:**

Regarding the guidance: Robert

Temple, Center for Drug Evaluation and Research (HFD-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-6758.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0864.

**SUPPLEMENTARY INFORMATION:** In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In May 1998, the ICH Steering Committee agreed that a draft guidance entitled "E10 Choice of Control Group in Clinical Trials" should be made available for public comment. The draft guidance is the product of the Efficacy Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

In accordance with FDA's good guidance practices (62 FR 8961, February 27, 1997), this document is now being called a guidance, rather than a guideline.

The draft guidance sets forth general principles that are relevant to all controlled trials and are especially pertinent to the major clinical trials intended to demonstrate drug (including biological drug) efficacy. The draft guidance includes a description of the five principal types of controls, a discussion of two important purposes of clinical trials, and an exploration of the critical issue of assay sensitivity, i.e., whether a trial could have detected a difference between treatments when there was a difference, a particularly important issue in noninferiority/equivalence trials. In addition, the draft guidance presents a detailed description of each type of control and considers, for each: (1) Its ability to minimize bias, (2) ethical and practical issues associated with its use, (3) its usefulness and the quality of inference in particular situations, (4) modifications of study design or combinations with other controls that can resolve ethical, practical, or inferential concerns, and (5) its overall advantages and disadvantages.

This draft guidance represents the agency's current thinking on the choice of control group in clinical trials. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before December 23, 1999, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>" or at CBRE's World Wide Web site at "<http://www.fda.gov/cber/publications.htm>".

The text of the draft guidance follows: