U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration

Maternal and Child Health Bureau Office of Epidemiology and Research

R40 Maternal and Child Health Research Program (MCHR)

Announcement Type: New, Revised Submission **Announcement Number:** HRSA-13-139

Catalog of Federal Domestic Assistance (CFDA) No. 93.110

FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2013

Application Due Date: September 12, 2012

Ensure your Grants.gov registration and passwords are current immediately.

Deadline extensions are not granted for lack of registration.

Registration may take up to one month to complete.

Release Date: July 26, 2012

Issuance Date: July 26, 2012

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Authority: Social Security Act, Title V, §501(a)(2) as amended (42 U.S.C. 701(a)(2))

EXECUTIVE SUMMARY

Maternal and Child Health Research Program (MCHR)

Thank you for your interest in the **R40** MCHR Competition. Grant support is available from the Division of Research, Office of Epidemiology and Research, part of the Maternal and Child Health Bureau (MCHB) of the Health Resources and Services Administration (HRSA) in the U.S. Department of Health and Human Services (DHHS). We are aware that preparation of this application will involve a considerable commitment of time and energy. **Please read the funding opportunity announcement carefully before completing the application.**

This funding opportunity announcement includes instructions for two (2) **separate grant competitions**:

- A. **R40** MCH Research (MCHR) Program supports applied research relating to maternal and child health services, that have the potential to improve health services and delivery of care for maternal and child health populations.
- B. **R40 Secondary Data Analysis Studies (SDAS) Program** supports applied research relating to maternal and child health services that utilizes exclusively the analysis of existing secondary data. These projects should have the potential to improve health services and delivery of care for maternal and child health populations.

Qualified Applicants: As cited in 42 CFR Part 51a.3(b), only public or nonprofit

institutions of higher learning and public or private nonprofit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health

care needs are eligible.

Number of Grants and Funds Available Per Vear:

MCH Research – Subject to the availability of

Funds Available Per Year: appropriations, approximately \$1,800,000 will be available to fund approximately six (6) grants per year for up to three (3) years (the ceiling amount of an individual award is \$300,000 total cost per

year).

Secondary Data Analysis Studies – Subject to the availability of appropriations, approximately \$1,000,000 is available to fund approximately ten (10) grants for one (1) year (the ceiling amount

of an individual award is \$100,000 total cost).

Application Due Date: MCH Research – September 12, 2012

Secondary Data Analysis Studies – September 12, 2012

Project Period: MCH Research -Approved projects will be funded effective

February 1, 2013 and will be awarded project periods of up to

three (3) years.

Secondary Data Analysis Studies – Approved projects will be funded effective February 1, 2013 and will be awarded a project

period of one (1) year.

Programmatic Assistance

Additional information related to the overall program issues or technical assistance may be obtained by contacting:

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5600 Fishers Lane, Room 18A-55, Rockville, MD 20857

Telephone: (301) 443-2207; Fax: (301) 443-4842 E-Mail: rharwood@hrsa.gov; hpark@hrsa.gov

Business, Administrative and Fiscal Inquiries

Applicants may obtain additional information regarding business, administrative, or fiscal issues related to this grant announcement by contacting:

Janene P. Dyson Grants Management Specialist Maternal Child & Health Systems Branch HRSA, Division of Grants Mgmt. Operations 5600 Fishers Lane, Room 11-103

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I. Funding Opportunity Description

1. Purpose

MCH Research (MCHR) Program

Within the R40 MCH Research Program, funding is available in FY 2013 to support approximately six (6) extramural multi-year research projects.

The R40 MCH Research Program supports applied research relating to maternal and child health services including services for children with special health care needs, which show promise of substantial contribution to advancement of the current knowledge pool, and when used in States and communities should result in health and health services improvements. Findings from the research supported by the MCH Research Program are expected to have potential for application in health care delivery programs for mothers and children. Research proposals should address critical MCH questions such as public health systems and infrastructure, health disparities, quality of care, and promoting the health of MCH populations, which also support the goals of the Health Resources and Services Administration. The "life course perspective" is currently being integrated into MCHB's strategic directions, and can serve as a helpful frame of reference for study proposals designed to address the critical MCH questions defined by the Bureau.

The Maternal and Child Health Bureau periodically reexamines its applied research agenda. In June 2003, the Bureau initiated the process of updating its research agenda by convening a work group to exchange information regarding the current and emerging issues of importance in the field. Members of the work group represented State and Federal agencies, institutions of higher learning and other organizations, who are prominent in the field and whose work has helped to advance the field. Based on the individual recommendations of these individuals, the Bureau developed the MCHB Strategic Research Issues (see Appendix B). The Bureau encourages translational research studies that specifically address issues related to MCHB investments and programs. Addressing one of the four strategic research issues is a review criterion worth up to 10 points in the overall score of an application.

Secondary Data Analysis Studies (SDAS) Program

Within the R40 MCH Research Program, funding is available in FY 2013 to support approximately ten (10) studies that analyze existing secondary MCH data.

2. Background

Maternal and Child Health Bureau and Title V of the Social Security Act: In 1935, Congress enacted Title V of the Social Security Act authorizing the Maternal and Child Health Services Programs. This legislation has provided a foundation and structure for assuring the health of mothers and children in our nation for more than 75 years. Title V was designed to improve health and assure access to high quality health services for present and future generations of mothers, infants, children and adolescents, including those with disabilities and chronic illnesses, with special attention to those of low income or with limited availability of health services.

Today, Title V is administered by the Maternal and Child Health Bureau (MCHB) which is a part of the Health Resources and Services Administration (HRSA) in the U.S. Department of Health and Human Services (HHS). Under Title V of the Social Security Act, the Maternal and Child Health Services Block Grant program has three components – Formula Block Grants to States, Special Projects of Regional and National Significance (SPRANS) and Community Integrated Service Systems (CISS) grants. Using these authorities, the MCHB has forged partnerships with States, the academic community, health professionals, advocates, communities and families to better serve the needs of our nation's children.

The mission of MCHB is to provide national leadership and to work, in partnership with States, communities, public-private partners, and families to strengthen the maternal and child health (MCH) infrastructure, assure the availability of medical homes, and build the knowledge and human resources, in order to assure continued improvement in the health, safety, and well-being of the MCH population. The MCH population includes all America's women, infants, children, adolescents and their families, including fathers and children with special health care needs (CSHCN).

The Extramural Maternal and Child Health Research Program (MCHR): The Maternal and Child Health Research Program is authorized by Title V, Section 501(a)(2); 42 U.S.C. 701(a)(2) of the Social Security Act, as amended, and is a component of the SPRANS. The program is administered by the Division of Research, Office of Epidemiology and Research, Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA). The MCH Research Program, built on over 40 years of experience, has supported investigations which have significantly influenced clinical management, organization and delivery of health care services, preventive care and early intervention for the maternal and child health population.

II. Award Information

1. Type of Award

Funding will be provided in the form of a grant.

2. Summary of Funding

Maternal and Child Health Research (MCHR) Program

The MCH Research Program will provide funding during Federal fiscal years 2013 – 2015. Approximately \$1,800,000 is expected to be available annually to fund approximately six (6) grantees. Applicants may apply for a ceiling amount of up to \$300,000 per year. The period of support is up to three (3) years. Funding beyond the first year is dependent on the availability of appropriated funds for MCHR in subsequent fiscal years, grantee satisfactory performance, and a decision that continued funding is in the best interest of the Federal Government.

Secondary Data Analysis Studies (SDAS)

The MCH Research Program will provide funding during Federal fiscal year 2013. Approximately \$1,000,000 is expected to be available to fund approximately ten (10) grantees. Applicants may apply for a ceiling amount of up to \$100,000. The period of support is one (1) year. Funding beyond the first year is dependent on the availability of appropriated funds for

MCHR in subsequent fiscal years, grantee satisfactory performance, and a decision that continued funding is in the best interest of the Federal government.

III. Eligibility Information

1. Eligible Applicants

As cited in 42 CFR Part 51a.3(b), only public or nonprofit institutions of higher learning and public or private nonprofit agencies engaged in research or in programs relating to maternal and child health and/or services for children with special health care needs are eligible.

2. Cost Sharing/Matching

Cost Sharing/Matching is not required for this program.

3. Other

Applications for the **R40 MCHR Program** must not exceed the \$300,000 ceiling amount of an individual award. Applications for the **R40 SDAS** must not exceed the \$100,000 ceiling amount of an individual award. These ceilings include both direct and indirect expenses.

Applications that exceed the ceiling amount or that request funding for more than the allowed project period will be considered non-responsive and will not be considered for funding under this announcement.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.3* will be considered non-responsive and will not be considered for funding under this announcement. Please see other limitations, including page limit and font/margin requirements in the HRSA User Guide (http://www.hrsa.gov/grants/apply/userguide.pdf) that may cause an application to be deemed non-responsive and removed from consideration. **In particular, applications that do not adhere to the 12-point font / 1" margin requirements, as specified in the HRSA User Guide, will be deemed non-responsive and will not be considered for funding under this announcement.**

A Principal Investigator (PI) cannot be named as the PI in multiple applications for either the R40 MCHR or R40 SDAS competitions. A PI cannot be named as PI on both an R40 MCHR and R40 SDAS application simultaneously. All applications that do not comply with these requirements will be deemed non-responsive, and will not be considered for funding under this announcement.

Due to funding limitations and the need for a diversified portfolio, the following additional eligibility requirements apply to **both the R40 MCHR and R40 SDAS Programs**:

Applications that overlap in project period with a currently funded MCH Research
project by the same Principal Investigator (PI) will not be considered for funding (i.e.,
a Principal Investigator cannot have two (2) R40 MCH Research grants in effect
simultaneously). A one-year no-cost extension of a current MCH Research project

- counts as part of the total project period during which an overlap in project period with a grant application is not allowable.
- A current PI of an MCH Research grant can serve for no more than 10% time on a new proposal in a capacity other than as Principal Investigator.
- Longitudinal follow-up studies will not be considered for funding under this announcement; i.e., a grantee who currently has or in the past has had an R40 grant cannot apply for a grant to follow longitudinally the population used in their previous R40 grant. Not excluded are: applications which include a longitudinal design within the proposed three-year project period; applications which involve analyzing pre-existing longitudinal data through the SDAS mechanism; and applications which involve collecting follow-up data on a population targeted in a grant funded by another agency.
- Analysis of secondary data previously collected by the applicant PI will not be considered for funding using the SDAS Program. SDAS applications should propose the use of large national pre-existing data sets or State or local administrative records.
- Secondary data analysis projects will not be considered for funding under the multiyear R40 MCH Research grant competition.
- Analysis of multiple datasets that require linkage or integration (e.g., combining administrative records from Medicaid, the child welfare system, and hospitals) will not be considered for funding under the multiyear R40 MCHR grant competition.
- Projects addressing autism will not be considered for the multiyear R40 MCHR and R40 SDAS competitions.
- Projects addressing oral health will not be considered for the multiyear R40 MCHR competition.

IV. Application and Submission Information

1. Address to Request Application Package

Application Materials and Required Electronic Submission Information

HRSA requires applicants for this funding opportunity announcement to apply electronically through Grants.gov. The registration and application process protects applicants against fraud and ensures that only authorized representatives from an organization can submit an application. Applicants are responsible for maintaining these registrations, which should be completed well in advance of submitting an application. All applicants *must* submit in this manner unless they obtain a written exemption from this requirement in advance by the Director of HRSA's Division of Grants Policy. Applicants must request an exemption in writing from **DGPWaivers@hrsa.gov**, and provide details as to why they are technologically unable to submit electronically through the Grants.gov portal. If requesting a waiver, include the following in the e-mail request: the HRSA announcement number for which the organization is seeking relief, the organization's DUNS number, the name, address, and telephone number of the organization and the name and telephone number of the Project Director as well as the Grants.gov Tracking Number (GRANTXXXX) assigned to the submission along with a copy of the "Rejected with Errors" notification as received from Grants.gov. HRSA and its Digital Services Operation (DSO) will only accept paper applications from applicants that received **prior written approval.** However, the application must still be submitted by the deadline.

Suggestion: submit application to Grants.gov at least two days before the deadline to allow for any unforeseen circumstances.

IMPORTANT NOTICE: CCR to be moved to SAM Effective July 30, 2012

CCR will transition to SAM at the end of July. CCR must stop accepting new data in order to successfully migrate the existing data into SAM. CCR's last business day is Tuesday, July 24, 2012. It will no longer accept new registrations or updates to current registrations after that time. The CCR Search capability will remain active through the transition to allow users to search for an entity's current registration status. SAM will be online for use Monday morning, July 30, 2012.

CCR will stop accepting data at 11:59 pm on Tuesday, July 24, 2012. **No new registrations can be submitted after that time. No updates to existing registrations can be submitted after that time.** Any registrations in process will be on hold until SAM goes live the morning of July 30, 2012. If users are in the middle of a registration, the data that has been submitted will be migrated to SAM.

If a record was scheduled to expire between July 16, 2012 and October 15, 2012, CCR is extending the expiration date by 90 days. The registrant will receive an e-mail notification from CCR when it extends the expiration date. The registrant will then receive standard e-mail reminders to update their record based on this <u>new</u> expiration date. Those future e-mail notifications will come from SAM.

SAM will reduce the burden on those seeking to do business with the government. Vendors will be able to log into one system to manage their entity information in one record, with one expiration date, through one streamlined business process. Federal agencies will be able to look in one place for entity pre-award information. Everyone will have fewer passwords to remember and see the benefits of data reuse as information is entered into SAM once and reused throughout the system.

Active CCR registration is a pre-requisite to the successful submission of grant applications!

Grants.gov strongly suggests visiting CCR prior to this change and checking the account status. Some things to consider are:

- When does the account expire?
- Does the organization need to complete the annual renewal of registration?
- Who is the eBiz POC? Is this person still with the organization?
- Does anything need to be updated?

To learn more about the switch from CCR to SAM, more information is available at https://www.bpn.gov/ccr/NewsDetail.aspx?id=2012&type=N. To learn more about SAM, please visit https://www.sam.gov.

Note: CCR or SAM information must be updated at least every 12 months to remain active (for both grantees and sub-recipients). As of August 9, 2011, Grants.gov began rejecting submissions from applicants with expired CCR registrations. This systematic enforcement will likely catch some applicants off guard. According to the CCR Website it can take 24 hours or

more for updates to take effect; or SAM Quick Guide for Grantees (https://www.sam.gov/sam/transcript/SAM Quick Guide Grants Registrations-v1.6.pdf), an entity's registration will become active after 3-5 days. Therefore, check for active registration well before the grant deadline.

An applicant can view their CCR Registration Status by visiting http://www.bpn.gov/CCRSearch/Search.aspx and searching by their organization's DUNS number. The CCR Website provides user guides, renewal screen shots, FAQs and other resources.

Applicants that fail to allow ample time to complete registration with CCR (prior to late July 2012) / SAM (starting late July 2012) and/or Grants.gov will not be eligible for a deadline extension or waiver of the electronic submission requirement.

All applicants are responsible for reading the instructions included in HRSA's *Electronic Submission User Guide*, available online at http://www.hrsa.gov/grants/apply/userguide.pdf. This Guide includes detailed application and submission instructions for both Grants.gov and HRSA's Electronic Handbooks. Pay particular attention to Sections 2 and 5 that provide detailed information on the competitive application and submission process.

Applicants are also responsible for reading the Grants.gov Applicant User Guide, available online at http://www.grants.gov/assets/ApplicantUserGuide.pdf. This Guide includes detailed information about using the Grants.gov system and contains helpful hints for successful submission.

Applicants must submit proposals according to the instructions in the Guide and in this funding opportunity announcement in conjunction with Application Form SF-424 Research and Related (SF-424 R&R). The forms contain additional general information and instructions for applications, proposal narratives, and budgets. The forms and instructions may be obtained by:

- 1) Downloading from http://www.grants.gov, or
- 2) Contacting the HRSA Digital Services Operation (DSO) at: HRSADSO@hrsa.gov

Each funding opportunity contains a unique set of forms and only the specific forms package posted with an opportunity will be accepted. Specific instructions for preparing portions of the application that must accompany the SF-424 R&R appear in the "Application Format Requirements" section below.

2. Content and Form of Application Submission

Application Format Requirements

The total size of all uploaded files may not exceed the equivalent of 80 pages when printed by HRSA. The total file size may not exceed 10 MB. The 80-page limit includes the abstract, project and budget narratives, attachments (appendices), and letters of commitment and support. Standard forms are NOT included in the page limit. **HRSA strongly urges applicants to print their application to ensure it does not exceed the 80-page limit. Do not reduce the size of**

the fonts or margins to save space. See the formatting instructions in Section 5 of the *Electronic Submission User Guide* referenced above.

Applications must be complete, within the 80-page limit, within the 10 MB limit, and submitted prior to the deadline to be considered under this announcement.

Submission of materials that were omitted from the Grants.gov submission after the deadline date is not allowed. Please note that all pages, even a page that is only partially filled with text, are counted by HRSA. For example, a biosketch that is $3\frac{1}{4}$ pages of text will be counted as 4 pages by HRSA.

Application Format

Applications for funding must consist of the following documents in the following order:

SF-424 R&R - Table of Contents

- A It is mandatory to follow the instructions provided in this section to ensure that the application can be printed efficiently and consistently for review.
- A Failure to follow the instructions may make the application non-responsive. Non-responsive applications will not be considered under this funding opportunity announcement.
- For electronic submissions, applicants only have to number the electronic attachment pages sequentially, resetting the numbering for each attachment, i.e., start at page 1 for each attachment. Do not attempt to number standard OMB approved form pages.
- ← For electronic submissions, no Table of Contents is required for the entire application. HRSA will construct an electronic table of contents in the order specified.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
SF-424 R&R Cover Page	Form	Pages 1 & 2.	Not counted in the page limit.
Pre-application	Attachment	Can be uploaded on page 2 of SF-424 R&R - Box 20.	Not Applicable to HRSA; Do not use.
SF-424 R&R Senior/Key Person Profile	Form	Supports 8 structured profiles (PD + 7 additional)	Not counted in the page limit.
Senior Key Personnel Biographical Sketches	Attachment	Can be uploaded in SF-424 R&R Senior/Key Person Profile form. One per each senior/key person. The PD/PI biographical sketch should be the first biographical sketch. Up to 8 allowed.	Counted in the page limit.
Senior Key Personnel Current and Pending Support	Attachment	Can be uploaded in SF-424 R&R Senior/Key Person Profile form.	Not Applicable to HRSA; Do not use.
Additional Senior/Key Person Profiles	Attachment	Can be uploaded in SF-424 R&R Senior/Key Person Profile form. Single document with all additional profiles.	Counted in the page limit.
Additional Senior/Key Personnel Biographical Sketches	Attachment	Can be uploaded in the Senior/Key Person Profile form. Single document with all additional sketches.	Counted in the page limit.
Additional Senior/Key Personnel Current and Pending Support	Attachment	Can be uploaded in the Senior/Key Person Profile form.	Not Applicable to HRSA; Do not use.
Project/Performance Site Location(s)	Form	Supports primary and 29 additional sites in structured form.	Not counted in the page limit.
Additional Performance Site Location(s)	Attachment	Can be uploaded in SF-424 R&R Performance Site Location(s) form. Single document with all additional site location(s).	Counted in the page limit.

Application Section	Form Type	Instruction	HRSA/Program Guidelines
Other Project Information	Form	Allows additional information and attachments.	Not counted in the page limit.
Project Summary/Abstract	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 7.	Required attachment. Counted in the page limit. Refer to funding opportunity announcement for detailed instructions.
Project Narrative	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 8.	Required attachment. Counted in the page limit. Refer to funding opportunity announcement for detailed instructions. If necessary, provide table of contents specific to this document only as the first page. Table of contents is not counted in the page limit.
Bibliography & References	Attachment	Can be uploaded in Other Project Information form, Box 9.	Optional. Counted in the page limit.
Facilities & Other Resources	Attachment	Can be uploaded in Other Project Information form, Box 10.	Required. Counted in the page limit.
Equipment	Attachment	Can be uploaded in Other Project Information form, Box 11.	Not required. Information pertaining to equipment should be included in the budget justification.
Other Attachments	Attachment	Can be uploaded in SF-424 R&R Other Project Information form, Box 12. Supports multiple.	Not Applicable to HRSA; Do not use.
SF-424 R&R Budget Period (1-5) - Section A – B	Form	Supports structured budget for up to 5 periods.	Not counted in the page limit.
Additional Senior Key Persons	Attachment	SF-424 R&R Budget Period (1-5) - Section A - B, End of Section A. One for each budget period.	Counted in the page limit.
SF-424 R&R Budget Period (1-5) - Section C – E	Form	Supports structured budget for up to 5 periods.	Not counted in the page limit.
Additional Equipment	Attachment	SF-424 R&R Budget Period (1-5) - Section C – E, End of Section C. One for each budget period.	Counted in the page limit.
SF-424 R&R Budget Period (1-5) - Section F – K	Form	Supports structured budget for up to 5 periods.	Not counted in the page limit.
SF-424 R&R Cumulative Budget	Form	Total cumulative budget.	Not counted in the page limit.
Budget Justification	Attachment	Can be uploaded in SF-424 R&R Budget Period (1-5) - Section F - K form, Box K. Only one consolidated budget justification for the	Required attachment. Counted in the page limit. Refer to funding opportunity announcement for detailed instructions.

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Application Section	Form Type	Instruction	HRSA/Program Guidelines
		project period.	Provide table of contents specific to this document only as the first page.
SF-424 R&R Subaward Budget	Form	Supports up to 10 budget attachments. This form only contains the attachment list.	Not counted in the page limit.
Subaward Budget Attachment 1-10	Extracted Form to be attached	Can be uploaded in SF-424 R&R Subaward Budget form, Box 1 through 10. Extract the form from the SF-424 R&R Subaward Budget form and use it for each consortium/ contractual/subaward budget as required by the program funding opportunity announcement. Supports up to 10.	Filename should be the name of the organization and unique. Not counted in the page limit. Budget justification narrative for each subaward organization IS counted in the page limit.
SF-424B Assurances for Non- Construction Programs	Form	Assurances for the SF-424 R&R package.	Not counted in the page limit.
Disclosure of Lobbying Activities (SF-LLL)	Form	Supports structured data for lobbying activities.	Not counted in the page limit.
Attachments Form	Form	Supports up to 15 numbered attachments. This form only contains the attachment list.	Not counted in the page limit.
Attachment 1-15	Attachment	Can be uploaded in Other Attachments form 1-15.	Refer to the attachment table provided below for specific sequence. Counted in the page limit.

- **○** To ensure that attachments are organized and printed in a consistent manner, follow the order provided below. Note that these instructions may vary across programs.
- © Evidence of Non-Profit status and invention related documents, if applicable, must be provided in the attachment form.
- Additional supporting documents, if applicable, can be provided using the available rows. Do not use the rows assigned to a specific purpose in the program funding opportunity announcement.
- A Merge similar documents into a single document. Where several documents are expected in one attachment, ensure that a table of contents cover page is included specific to the attachment. Table of Contents page will not be counted in the page limit.
- Limit the file attachment name to under 50 characters. Do not use any special characters (e.g., %, /, #) or spacing in the file name or word separation. (The exception is the underscore (_) character.) Attachments will be rejected by Grants.gov if they include special characters or attachment names greater than 50 characters.

Attachment Number	Attachment Description (Program Guidelines)
Attachment 1	Letters of Agreement/Letters of Support, as applicable
Attachment 2	Key publications or condensed citations with abstracts, as applicable
Attachment 3	Surveys, questionnaires, data collection instruments, clinical protocols, as applicable

Attachment Number	Attachment Description (Program Guidelines)
Attachment 4	Explanation on delinquent Federal debt, if applicable
Attachment 5	Evidence of Non-profit status and invention related documents, if applicable

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Application Format

i. Application Face Page

Complete Standard Form 424 Research and Related (SF-424 R&R) provided with the application package. Prepare according to instructions provided in the form itself. For information pertaining to the Catalog of Federal Domestic Assistance, the CFDA Number is 93.110.

DUNS Number

All applicant organizations (and subrecipients of HRSA award funds) are required to have a Data Universal Numbering System (DUNS) number in order to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a unique nine-character identification number provided by the commercial company, Dun and Bradstreet. There is no charge to obtain a DUNS number. Information about obtaining a DUNS number can be found at http://fedgov.dnb.com/webform or call 1-866-705-5711. Please include the DUNS number in form SF-424 R&R – item 5 on the application face page. Applications will not be reviewed without a DUNS number. Note: A missing or incorrect DUNS number is the number one reason for applications being "Rejected for Errors" by Grants.gov. HRSA will not extend the deadline for applications with a missing or incorrect DUNS number. Applicants should take care in entering the DUNS number in the application.

Additionally, the applicant organization (and any subrecipient of HRSA award funds) is required to register annually with the Central Contractor Registration (CCR) (soon to be SAM) in order to conduct electronic business with the Federal Government. CCR (or SAM) registration must be maintained with current, accurate information at all times during which an entity has an active award or an application or plan under consideration by HRSA. It is extremely important to verify that the applicant organization CCR (or SAM) registration is active and the Marketing Partner ID Number (MPIN) is current. Information about registering with the CCR can be found at http://www.ccr.gov. Please see Section IV of this funding opportunity announcement for IMPORTANT NOTICE: CCR to be moved to SAM starting July 30, 2012.

ii. Table of Contents

The application should be presented in the order of the Table of Contents provided earlier. Again, for electronic applications no table of contents is necessary as it will be generated by the system. (Note: the Table of Contents will not be counted in the page limit.)

iii. Budget

Complete the Research and Related Budget Form provided with the application package.

Please complete the Research & Related Budget Form (Sections A – K) and the Cumulative Budget) for each budget period. Upload the Budget Justification Narrative for the entire project period (<u>all</u> budget periods) in Section K of the Research & Related Budget Form. Following completion of Budget Period 1, click on the "NEXT PERIOD" button on the final page to allow for completion of Budget Period 2. Repeat this instruction to complete additional Budget Periods, as needed.

The Cumulative Budget is automatically generated and provides the total budget information for the entire project period grant request. Errors found in the Cumulative Budget must be

corrected within the incorrect field(s) in Budget Period 1, 2, or 3; corrections cannot be made to the Cumulative Budget itself.

Please complete the R&R Subaward Budget Attachment(s) Form for each contractual arrangement. NOTE: Subaward Budget Attachment Forms $\underline{DO\ NOT}$ count toward the page limit. These forms will represent the full project period of Federal assistance requested. A budget justification must be uploaded for each contractual arrangement and is included in the application page count. All budgets must be well justified, with explanations of each line item. NOTE: Contractual costs entered in the R&R Subaward Budget Attachment(s) Form do not automatically get included in the Cumulative Budget page for each budget period. Therefore, you must include the amount for contractual costs in Section F – K, #5 Subawards/Consortium/Contractual costs of each budget period. This will ensure that the cumulative budget page for each budget period will correctly reflect the entire cost for each budget period.

Salary Limitation:

The Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, limits the salary amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is \$179,700. This amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under a HRSA grant or cooperative agreement.

As an example of the application of this limitation: If an individual's base salary is \$350,000 per year plus fringe benefits of 25% (\$87,500) and that individual is devoting 50% of their time to this award, their base salary should be adjusted to \$179,700 plus fringe of 25% (\$44,925) and a total of \$112,312.50 may be included in the project budget and charged to the award in salary/fringe benefits for that individual. See the breakdown below:

Individual's <i>actual</i> base full time salary: \$350,000		
50% of time will be devoted to project		
Direct salary	\$175,000	
Fringe (25% of salary)	\$43,750	
Total	\$218,750	
Amount that may be alois	med on the application hudget due to the	
legislative salary limitation	salary adjusted to Executive Level II: \$179,700	
legislative salary limitatio Individual's base full time	on: salary <i>adjusted</i> to Executive Level II: \$179,700	
legislative salary limitation Individual's base full time 50% of time will be devote	salary <i>adjusted</i> to Executive Level II: \$179,700 ed to the project	

iv. Budget Justification

Provide a narrative that explains the amounts requested for each line in the budget. The budget justification should specifically describe how each item will support the achievement

of proposed objectives. The budget period is for ONE year. However, the applicant **must** submit one-year budgets for each of the subsequent budget periods within the requested project period at the time of application. Line item information must be provided to explain the costs entered in the Research and Related budget form. Be very careful about showing how each item in the "other" category is justified. For subsequent budget years, the justification narrative should highlight the changes from year one or clearly indicate that there are no substantive budget changes during the project period. The budget justification MUST be concise. Do NOT use the justification to expand the project narrative.

Budget for Multi-Year Award (N/A to Secondary Data Analysis Studies) This announcement is inviting applications for project periods up to three (3) years (MCHR Program).

Awards, on a competitive basis, will be for a one-year budget period; although the project period may be up to three (3) years (MCHR Program). Submission and HRSA approval of the Progress Report(s) and any other required submission or report is the basis for the budget period renewal and release of subsequent year funds. Funding beyond the one-year budget period but within the three-year project period is subject to availability of funds, satisfactory progress of the awardee, and a determination that continued funding would be in the best interest of the Federal Government.

Include the following in the Budget Justification narrative:

Personnel Costs: Personnel costs should be explained by listing each staff member who will be supported from funds, name (if possible), position title, percentage of full-time equivalency, and annual salary. Reminder: Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II or \$179,700. An individual's base salary, per se, is NOT constrained by the legislative provision for a limitation of salary. The rate limitation simply limits the amount that may be awarded and charged to HRSA grants and cooperative agreements. Please provide an individual's actual base salary if it exceeds the cap. See the sample below.

Sample:

Name	Position Title	% of	Annual	Amount
		FTE	Salary	Requested
J. Smith	Chief Executive Officer	50	\$179,700*	\$89,850
R. Doe	Nurse Practitioner	100	\$75,950	\$75,950
D. Jones	Data/AP Specialist	25	\$33,000	\$8,250

^{*}Actual annual salary = \$350,000

Fringe Benefits: List the components that comprise the fringe benefit rate, for example health insurance, taxes, unemployment insurance, life insurance, retirement plans, and tuition reimbursement. The fringe benefits should be directly proportional to that portion of personnel costs that are allocated for the project. (If an individual's base salary exceeds the legislative salary cap, please adjust fringe accordingly.)

Travel: List travel costs according to local and long distance travel. For local travel, the mileage rate, number of miles, reason for travel and staff member/consumers completing the travel should be outlined. The budget should also reflect the travel expenses

associated with participating in meetings and other proposed trainings or workshops. Travel outside of the U.S. is not supported for MCH Research Program projects.

Equipment: List equipment costs and provide justification for the need of the equipment to carry out the program's goals. Extensive justification and a detailed status of current equipment must be provided when requesting funds for the purchase of computers and furniture items that meet the definition of equipment (a unit cost of \$5,000 or more and a useful life of one or more years).

Supplies: List the items that the project will use. In this category, separate office supplies from medical and educational purchases. Office supplies could include paper, pencils, and the like; medical supplies are syringes, blood tubes, plastic gloves, etc., and educational supplies may be pamphlets and educational videotapes. Remember, these supply subcategories (office, medical, educational) must be listed separately.

Contractual: Applicants are responsible for ensuring that their organization or institution has in place an established and adequate procurement system with fully developed written procedures for awarding and monitoring all contracts. Applicants must provide a clear explanation as to the purpose of each contract, how the costs were estimated, and the specific contract deliverables. Reminder: recipients must notify potential subrecipients that entities receiving subawards must be registered in CCR (or SAM starting July 30, 2012 - See Section IV of this document for more SAM details) and provide the recipient with their DUNS number.

Consultants: Give name and institutional affiliation, qualifications of each consultant, if known, and indicate the nature and extent of the consultant service to be performed. Include expected rate of compensation and total fees, travel, per diem, or other related costs for each consultant.

Other: Put all costs that do not fit into any other category into this category and provide an explanation of each cost in this category. In some cases, rent, utilities and insurance fall under this category if they are not included in an approved indirect cost rate.

Applicants may include the cost of access accommodations as part of their project's budget, including sign interpreters, plain language and health literate print materials in alternate formats (including Braille, large print, etc.); and cultural/linguistic competence modifications such as use of cultural brokers, translation or interpretation services at meetings, clinical encounters, and conferences, etc.

Indirect Costs: Indirect costs are those costs incurred for common or joint objectives which cannot be readily identified but are necessary to the operations of the organization, e.g., the cost of operating and maintaining facilities, depreciation, and administrative salaries. For institutions subject to OMB Circular A-21, the term "facilities and administration" is used to denote indirect costs. If an organization applying for an assistance award does not have an indirect cost rate, the applicant may wish to obtain one through HHS's Division of Cost Allocation (DCA). Visit DCA's website at: http://rates.psc.gov/ to learn more about rate agreements, the process for applying for them, and the regional offices which negotiate them. The indirect cost rate agreement will not count toward the page limit.

v. Staffing Plan and Personnel Requirements

Applicants must present a staffing plan and provide a justification for the plan that includes education and experience qualifications and rationale for the amount of time being requested for each staff position. Position descriptions that include the roles, responsibilities, and qualifications of proposed project staff must be included in the "Budget Narrative" section that will be uploaded in SF-424 R&R Budget Period – Section F – K Form, Box K. The staffing plan information should be included in the Budget Narrative, under Personnel costs. A current PI of an MCH Research grant can serve for no more than 10% time on a new proposal in a capacity other than as Principal Investigator.

If the project is collaborative or has multiple investigators, the staffing plan should describe the complementary and integrated expertise of the investigators and show that the leadership approach, governance and organizational structure are appropriate for the project. The staffing plan should reflect the commitment of the research team in conducting and completing the study. Copies of biographical sketches for all Senior/Key Personnel and Other Significant Contributors that will be assigned to work on the proposed project must also be submitted as an attached file to each SF-424 R&R Senior/Key Person Profile. The Biographical Sketch should not exceed four pages per person.

Biographical sketches should follow the format described below:

- A. Professional Information: Name, Position Title, Education/Training including: institution and location, degree, month/year degree attained, field of study.
- B. When applicable, biographical sketches should include training, language fluency, and experience working with culturally and linguistically diverse populations.
- C. **Personal Statement.** Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PD/PI, mentor) in the project that is the subject of the application.
- D. **Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.
- E. Peer-reviewed publications or manuscripts in press (in chronological order). Applicants are encouraged to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research. Citations that are publicly available in a free, online format may include URLs along with the full reference.
- F. **Research Support.** List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the Senior/Key Person identified on the Biographical Sketch. **You must also include percent effort on all ongoing research projects listed**.

Do not confuse "Research Support" with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. In contrast, "Other Support" information is required for all applications that are selected to receive grant awards. HRSA staff will request complete and up-to-date "other support" information from you after peer review. This information will be used to check that the proposed research has not already been Federally-funded.

vi. Assurances

Complete Application Form SF-424B Assurances – Non-Construction Programs provided with the application package.

If research involving human subjects is anticipated, applicants must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR 46), available online at www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

vii. Certifications

Use the Certifications and Disclosure of Lobbying Activities Application Form provided with the application package. Any organization or individual that is indebted to the United States, and has a judgment lien filed against it for a debt to the United States, is ineligible to receive a Federal grant. By signing the SF-424 R&R, the applicant is certifying that they are not delinquent on Federal debt in accordance with OMB Circular A-129. (Examples of relevant debt include delinquent payroll or other taxes, audit disallowances, guaranteed and direct student loans, benefits that were overpaid, etc.). If an applicant is delinquent on Federal debt, they should attach an explanation that includes proof that satisfactory arrangements have been made with the Agency to which the debt is owed. This explanation should be uploaded as **Attachment 4**.

Please note the following requirements related to research misconduct:

Each institution that receives or applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by 42 CFR Part 93, "Public Health Service Policies on Research Misconduct."

In checking the "I agree" box on line 17 of the SF424 (R&R) Cover Component, the Authorized Organizational Representative of the applicant organization certifies that:

- The institution will comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 93, Subpart A
- 2) The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 93, Subpart A;
- 3) The institution will provide its policies and procedures to the Office of Research Integrity upon request; and

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4) The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to all PHS awardees by the Office of Research Integrity each January.

Research Misconduct is defined by the Public Health Service as "fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results."

- a) Fabrication is making up data or results and recording or reporting them.
- b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- d) Research misconduct does not include honest error or differences of opinion.

For further information, please contact:

U.S. Department of Health and Human Services Office of Research Integrity 1101 Wootton Parkway, Suite 750 Rockville, MD 20852

Email: AskORI@osophs.dhhs.gov

Phone: (240) 453-8200 Fax: (301) 443-5351

viii. Project Abstract

Provide a summary of the application. Because the abstract is often distributed to provide information to the public and Congress, please prepare this so that it is clear, accurate, concise, and without reference to other parts of the application. It must include a brief description of the proposed project including the needs to be addressed, the proposed services, and the population group(s) to be served.

Please place the following at the top of the abstract:

- Project Title
- Principal Investigator Name
- Applicant Organization Name

The project abstract must be single-spaced and limited to one page in length. In describing the research design and methods within the abstract, be careful to include data collection methods. From the list of key terms found in Appendix C, select a maximum of eight significant key terms that describe your project. You can also select an additional 9th key term that is not found in Appendix C. Include the selected significant key terms at the end of your abstract. Briefly state the principal needs and problems which are addressed by the project, including the project's relationship to current MCHB Strategic Research Issues (Appendix B). A complete and informative abstract is critical to the review of your application.

ix. Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

Use the following section headers for the Narrative:

<u>A. Introduction</u> (for resubmission only): Only a single amendment to the original application (called a resubmission application) will be accepted.

NOTE: FOR RESUBMISSIONS, MARK THE APPLICATION AS "RESUBMISSION" ON THE SF-424 R&R.

For a resubmission of a previously reviewed proposal, begin the Introduction by specifying that it is a resubmission; state the application/tracking number of the prior submission, its title, and HRSA announcement number of the prior submission.

Example: This is a resubmission of application #, Determinants of Racial Disparities in Infant Mortality Rates, that was submitted for HRSA-11-016. There is no time limit for a resubmission application. The following requirements pertain to a resubmission:

- The PD/PI(s) must make significant changes to the application.
- An Introduction must be included that summarizes the substantial additions, deletions, and changes to the application. The Introduction must also include a response to the issues and criticism raised in the Summary Statement. The Introduction should not exceed three pages.
- The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or change of typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the Introduction. The Preliminary Studies/Progress Report section should incorporate work completed since the prior version of the application was submitted.

B. Specific Aims (Related Review Criteria: Need, Response, Impact, Evaluative Measures):

List succinctly the specific objectives of the specific research proposed, for example, to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology. State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

Write a statement of the research problem, indicate the relevance of the problem to maternal and child health or children with special health care needs programs and identify the envisioned application of findings to the clinical management of mothers and children and/or the ways that maternal and child health services are organized and delivered. Identify relevance to MCHB Strategic Research Issues (Appendix B) and relationship to specific Healthy People 2020 objectives. The applicant is responsible for explaining the project's relevance to an MCHB Strategic Research Issue.

Hypothesis and Specification of Variables. Present the specific questions that are to be answered by the study. These should include not only predictions as to findings

(hypotheses) but also justifications for the predictions. A summary table of the variables, classified as independent, intervening, mediating, and dependent, etc. should be presented, specifying the nature of the variables, the measures to be employed as indicators for these variables, and the units and levels of measurement of the indicators. If possible, construct and present a model or graphical representation of the set of relationships held to be operative among the variables. Make sure that there is congruence between the associations depicted by the graphic model, the table of variables, the statement of hypotheses, and the plan for data analysis.

C. Research Strategy:

Organize the Research Strategy in the specified order using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.

The Research Strategy section (Significance, Innovation, Approach) is limited to 12 pages in length for R40 MCHR. For SDAS applications, this section is limited to 6 pages in length. Applications that exceed these page limits in the Research Strategy section will be deemed non-responsive, and will not be considered for funding under this announcement.

- (a) Significance (Related Review Criteria: Need, Response, Impact)
 - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
 - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
 - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
- (b) Innovation (Related Review Criteria: Response, Evaluative Measures)
 - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
 - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
 - Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- (c) Approach (Related Review Criteria: Evaluative Measures)
 - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
 - Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Point any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

As applicable, also include the following information as part of the Research Strategy, keeping within the three sections listed above: Significance, Innovation, and Approach.

Preliminary Studies for New Applications: For new applications, include information on Preliminary Studies as part of the Approach section. Use this section to provide an account of the PD/PI's preliminary studies pertinent to this application, including his/her preliminary experience with and outreach to the proposed racial/ethnic group members. This information will also help to establish the experience and competence of the investigator to pursue the proposed project. Preliminary data often aid the reviewers in assessing the likelihood of the success of the proposed project.

<u>D. Tentative Sequence or Timetable (Related Review Criteria: Evaluative Measures):</u>

Provide a tentative sequence or timetable for the project. Provide assurance that the research team will conduct the study as designed. Due to the competitive nature of the MCH Research Program grant competitions and limited availability of funding, it is important that the applicant address the feasibility of conducting and completing the study as proposed. Once funded, it is critical that the study is implemented and completed as proposed and approved.

E. Financing (Related Review Criteria: Support Requested):

State whether this proposal has been submitted or will be submitted to any other Federal agency or private foundation for consideration and review. Explain the amount of support available or expected for this project from other sources.

F. Protection of Human Subjects (Related Review Criteria: Evaluative Measures):

If human subject are involved, the project should be in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR Part 46) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). See http://mchb.hrsa.gov/research/grant-p2.asp under Phase 2 for specific instructions on preparing the human subjects section of the application.

This section is required for applicants answering "yes" to the question "Are human subjects involved?" on the R&R Other Project Information form. If the answer is "No" to the question but the proposed research involves human specimens and/or data from subjects, applicants must provide a justification in this section for the claim that no human subjects are involved.

Discuss plans to seek Institutional Review Board (IRB) approval. IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Research Strategy.

G. Targeted/Planned Enrollment (Related Review Criteria: Evaluative Measures):

Provide details about the Targeted/Planned Enrollment for the study. Information should include targeted/planned enrollment totals by:

- Ethnic Category (Hispanic Heritage): "Hispanic or Latino" or "Not Hispanic or Latino"
 - o Gender distribution within each Ethnic Category (Hispanic Heritage)
 - o Total planned enrollment by Ethnic Category (Hispanic Heritage)
- Racial Categories
 - o American Indian/Alaska Native
 - o Asian
 - o Native Hawaiian or Other Pacific Islander
 - o Black or African American
 - o White
 - o Gender distribution within each racial category
 - o Total planned enrollment by racial category

The "Ethnic Category (Hispanic Heritage): Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects. Also list any proposed racial/ethnic subpopulations, if applicable. The "Total Planned Enrollment" means the number of subjects that are expected to be enrolled during the entire period of the study and are needed to evaluate the research question. The "Total Planned Enrollment" will be reported in two ways in the table: by self-reported "Ethnic Category (Hispanic Heritage)" and by self-reported "Racial Categories."

Describe how the project will assure cultural competence. For **R40 MCHR**, describe how the project will assure cultural competence in terms of including individuals from the study population in the planning and implementation of the research project and in adapting the research methodology to reflect an understanding of and valuing the culture of the study population. For **R40 SDAS**, describe how the analytic plan will reflect an understanding of and valuing the culture of the study population.

H. Dissemination Plan (Related Review Criteria: Impact):

Describe plans for dissemination of project results. State whether the project results are regional or national in scope and if they are replicable. It is expected that **R40 MCHR** research grantees will produce at least 3 peer-reviewed publications per study and that **R40 SDAS** research grantees will produce at least 2 peer-reviewed publications resulting from their MCH Research project. The dissemination plan should include information on how you will accomplish this minimum number of publications. Past MCH Research Program grantees should demonstrate publications from their previous MCH research grant. (NOTE: Peer-reviewed publications are the cardinal measure of success of the MCH Research Program).

<u>I.</u> <u>Environment (Related Review Criteria: Resources/Capabilities)</u>: This information is used to assess the capability of the organizational resources available to perform the effort proposed. NOTE: The SF-424 R&R Table of Contents Page refers to Environment as "Facilities & Other Resources." This section on "Environment" can be included as an attachment in the Other Project Information Form, box 10 or included as part of the research narrative.

- Identify the facilities to be used (laboratory, clinical, computer, office, other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work.
- Describe how the scientific environment in which the research will be done
 contributes to the probability of success (e.g., institutional support, physical
 resources, and intellectual rapport). In describing the scientific environment in
 which the work will be done, discuss ways in which the proposed study will
 benefit from unique features of the scientific environment or subject populations
 or will employ useful collaborative arrangements.
- For Early Stage Investigators, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support.
- If there are multiple performance sites, describe the resources available at each site.

x. Program Specific Forms

1) Performance Standards for Special Projects of Regional or National Significance (SPRANS) and Other MCHB Discretionary Projects

The Health Resources and Services Administration (HRSA) has modified its reporting requirements for SPRANS projects, CISS projects, and other grant programs administered by the Maternal and Child Health Bureau (MCHB) to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for Federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for States have also been established under the Block Grant provisions of Title V of the Social Security Act, the MCHB's authorizing legislation. Performance measures for other MCHB-funded grant programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect. An electronic system for reporting these data elements has been developed and is now available.

2) Performance Measures for the **MCH Research Program** and Submission of Administrative Data

To prepare successful applicants for their reporting requirements, the administrative forms and performance measures are presented in Appendix A of this funding opportunity announcement. In summary, the forms and performance measures for this program are:

• Form 1, MCHB Project Budget Details

- Form 2, Project Funding Profile
- Form 4, Project Budget and Expenditures by Types of Services ((Note, funds for the R40 MCH Research Program would fit under "Infrastructure Building Services")
- Form 7, Discretionary Grant Project Summary Data
- Form 8. Abstract for Research Projects
- Performance Measure 03, The percentage of MCHB-funded projects submitting and publishing findings in peer-reviewed journals
- Performance Measure 10, The degree to which MCHB-funded programs have incorporated cultural and linguistic competence elements into their policies, guidelines, contracts and training.
- Products, Publications and Submissions Data Form

xi. Attachments

Please provide the following items to complete the content of the application, as applicable. Please note that these are supplementary in nature, and are not intended to be a continuation of the project narrative. Unless otherwise noted, attachments count toward the application page limit. **Each attachment must be clearly labeled**.

Attachment 1: Letters of Agreement/Letters of Support

Provide any documents that describe working relationships between the applicant agency and other agencies and programs cited in the proposal. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the subcontractors and any deliverable. Include only letters of support which specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). Letters of agreement and letters of support must be dated.

Attachment 2: Key publications or condensed citations with abstracts.

Do not include unpublished theses, or abstracts/manuscripts **submitted** (but not yet accepted) for publication.

Attachment 3: Surveys, questionnaires, data collection instruments, clinical protocols. Surveys, questionnaires, and other data collection instruments; clinical protocols and informed consent documents may be submitted as an Attachment as necessary.

Attachment 4: Explanation on delinquent Federal debt, if applicable.

Attachment 5: Evidence of Non-Profit status and invention related documents, if applicable.

3. Submission Dates and Times

Application Due Date

The due date for applications under this funding opportunity announcement is *September 12*, 2012 at 8:00 P.M. ET. Applications completed online are considered formally submitted when the application has been successfully transmitted electronically by the organization's Authorized Organization Representative (AOR) through Grants.gov and validated by Grants.gov on or before the deadline date and time.

Receipt acknowledgement: Upon receipt of an application, Grants.gov will send a series of email messages to document the progress of an application through the system.

- 1) The first will confirm receipt in the system;
- 2) The second will indicate whether the application has been successfully validated or has been rejected due to errors;
- 3) The third will be sent when the application has been successfully downloaded at HRSA; and
- 4) The fourth will notify the applicant of the Agency Tracking Number assigned to the application.

The Chief Grants Management Officer (CGMO) or designee may authorize an extension of published deadlines when justified by circumstances such as natural disasters (e.g., floods or hurricanes) or other disruptions of services, such as a prolonged blackout. The CGMO or designee will determine the affected geographical area(s).

Late applications:

Applications which do not meet the criteria above are considered late applications and will not be considered in the current competition.

4. Intergovernmental Review

The MCH Research Program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100.

5. Funding Restrictions

Funds under this announcement for R40 MCHR and R40 SDAS may not be used for the following purposes: foreign travel, tuition remission for graduate research assistants.

Extramural MCH Research Program

Applicants may request funding for a project period of up to three (3) years, at no more than \$300,000 total cost (direct plus indirect expenses) per year.

Awards for the first year are subject to the availability of appropriations. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the government.

Secondary Data Analysis Studies

Applicants may request funding for a project period of one (1) year, at no more than \$100,000 total cost (direct plus indirect expenses).

Salary Limitation: The Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, limits the salary amount that may be awarded and charged to HRSA grants and cooperative agreements. Award funds may not be used to pay the salary of an individual at a rate in excess of Executive Level II. The Executive Level II salary of the Federal Executive Pay scale is \$179,700. This amount reflects an individual's base salary <u>exclusive</u> of fringe and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This salary limitation also applies to subawards/subcontracts under a HRSA grant or cooperative agreement.

Per Division F, Title V, Section 503 of the Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011 (a) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself. (b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government. (c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

Per Division F, Title V, Section 523 of the Consolidated Appropriations Act, 2012 (P.L. 112-74) enacted December 23, 2011, no funds appropriated in this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

6. Other Submission Requirements

As stated in Section IV.1, except in very rare cases HRSA will no longer accept applications in paper form. Applicants submitting for this funding opportunity are *required* to submit *electronically* through Grants.gov. To submit an application electronically, please use the APPLY FOR GRANTS section at http://www.grants.gov. When using Grants.gov applicants 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.

It is essential that organizations *immediately register* in Grants.gov and become familiar with the Grants.gov site application process. Applicants that do not complete the registration process, will be unable to submit an application. The registration process can take up to one month.

To be able to successfully register in Grants.gov, it is necessary to complete all of the following required actions:

- Obtain an organizational Data Universal Numbering System (DUNS) number
- Register the organization with Central Contractor Registration (CCR) (or System for Award Management (SAM) starting July 30, 2012. See Section IV of this document for more SAM details.)

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- Identify the organization's E-Business Point of Contact (E-Biz POC)
- Confirm the organization's CCR (or SAM starting July 30, 2012) "Marketing Partner ID Number (M-PIN)" password
- Register and approve an Authorized Organization Representative (AOR)
- Obtain a username and password from the Grants.gov Credential Provider

Instructions on how to register, tutorials and FAQs are available on the Grants.gov web site at http://www.grants.gov. Assistance is also available 24 hours a day, 7 days a week (excluding Federal holidays) from the Grants.gov help desk at support@grants.gov or by phone at 1-800-518-4726. Applicants should ensure that all passwords and registration are current well in advance of the deadline.

It is incumbent on applicants to ensure that the AOR is available to submit the application to HRSA by the published due date. HRSA will <u>not</u> accept submission or re-submission of incomplete, rejected, or otherwise delayed applications after the deadline. Therefore, an organization is urged to submit an application in advance of the deadline. If an application is rejected by Grants.gov due to errors, it must be corrected and resubmitted to Grants.gov before the deadline date and time. Deadline extensions will <u>not</u> be provided to applicants who do not correct errors and resubmit before the posted deadline.

If, for any reason, an application is submitted more than once prior to the application due date, HRSA will only accept the applicant's last validated electronic submission prior to the Grants.gov application due date as the final and only acceptable application.

Tracking an application: It is incumbent on the applicant to track their application by using the Grants.gov tracking number (GRANTXXXXXXXX) provided in the confirmation email from Grants.gov. More information about tracking an application can be found at https://apply07.grants.gov/apply/checkApplStatus.faces. Be sure the application is validated by Grants.gov prior to the application deadline.

V. Application Review Information

1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist the applicant in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist the applicant in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation. Review criteria are outlined below with specific detail and scoring points.

NOTE: The terms *research project* and *study* are used interchangeably.

Review Criteria are used to review and rank applications. The R40 Extramural MCH Research Program and R40 Secondary Data Analysis Studies Program have six (6) review criteria:

Criterion 1.	Need	10 points
Criterion 2.	Response	20 points
Criterion 3.	Evaluative Measures	40 points
Criterion 4.	<u>Impact</u>	10 points
Criterion 5.	Resources/Capabilities	10 points
Criterion 6.	Support Requested	10 points

TOTAL: 100 points

Criterion 1: NEED (10 points) (Related Program Narrative Section: Specific Aims)

The extent to which the application describes an important strategic MCH research problem/issue and associated contributing factors, as described in the MCHB Strategic Research Issues (Appendix B). The Bureau strongly encourages research studies that specifically address issues related to MCHB investments and programs, particularly those with expected broad public health impact.

- The extent to which the research project addresses an important MCH problem or a critical barrier to progress in the field.
- The extent to which the research project addresses an MCHB Strategic Research Issue (Appendix B).
- The extent to which the research project identifies its relationship to specific Healthy People 2020 objectives. (See VI. Award Administration Information on Healthy People 2020).

Criterion 2: RESPONSE (20 points) (Related Program Narrative Section: Specific Aims, Research Strategy: Significance and Innovation)

The extent to which the proposed project responds to the "Purpose" included in the program description. The strength of the proposed goals and objectives and their relationship to the identified project. The extent to which the scientific activities described in the application are capable of addressing the problem and attaining the project objectives.

- The extent to which the overall scientific approach is thoughtful, logical and original.
- The extent to which the investigators demonstrate awareness of previous and current work in the area of the project. The extent to which the cited literature is pertinent to the research problem and provides a rationale for the research.
- The extent to which the hypotheses are logically derived from the literature, clearly stated, and are related to the defined problem.
- The extent to which the goals and objectives clear, concise and appropriate.
- The extent to which scientific knowledge, technical capability, and/or clinical practice will be improved, if the aims of the project are achieved.
- The extent to which successful completion of the aims will change the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field.
- The extent to which the application challenges and seeks to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- The extent to which the concepts, approaches or methodologies, instrumentation, or interventions are novel to one field of research or novel in a broad sense.

• The extent to which a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions is proposed.

Criterion 3: EVALUATIVE MEASURES (40 points) (Related Program

Narrative Section: Specific Aims, Research Strategy: Innovation and Approach, Protection of Human Subjects, Targeted/Planned Enrollment Table)

The effectiveness of the methods proposed to conduct the research project. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

Proposed measures must be able to assess to what extent the project objectives have been met. Are potential problems, alternative strategies, and benchmarks for success presented? How will particularly risky aspects of the project be managed? Is the project feasible as proposed?

If the project involves clinical research, are plans included for: 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders? Is the proposed inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Scientific and Technical Merit:

- The appropriateness of the research plan and methodologies described.
- The extent to which the research plan is coherent as a whole.
- The extent to which the proposed project is feasible in terms of subject recruitment, as well as in terms of conducting and completing the study as proposed within the given time frame

Tests and Measurements:

- The extent to which data gathering procedures are described.
- If new data are to be collected, the extent to which instruments have been selected or developed and are adequate and appropriate.
- The extent to which adequate attention is given to reliability and validity (psychometric properties).
- If secondary analysis of existing data is proposed, the extent to which the data are available to the investigator and are appropriate for this study. The extent to which the secondary data provide convincing validity for intended measurements, e.g., self-reported blood pressure, parent-reported anthropometric data. (NOTE: The SDAS grant program does not support analysis of data previously collected by the applicant PI).

Study Design:

- The appropriateness of the study design to answer the research questions.
- The degree to which proper controls are included.
- The extent to which the description of the design is explicit enough to permit replication.
- The extent to which all the significant threats to internal and external validity of the design have been adequately acknowledged and addressed.
- The extent to which the method of randomization, if used, is clearly described and criteria for entering the study are well defined.

Population Description and Sampling Plan:

- The degree to which the study population is described.
- The degree to which the sampling design is appropriate.
- The degree to which the sample size is adequate and justified in terms of statistical power.
- The extent to which expected differences between groups are defined in terms of statistical as well as clinical significance.
- The extent to which there is a basis for anticipating the quality of sample estimates and the degree to which the quality is adequate for the purpose of the study.

Plan for Data Analysis:

- The degree to which plans for data analysis are presented in detail.
- The extent to which the plans describe the process of data analysis and the rationale for the sequence of steps to be taken.
- The appropriateness of the plans to the nature of the data, design and samples.
- The appropriateness of the statistical methods.
- The extent to which sufficient time is allocated for data analysis and reporting.

Protection of Human Subjects:

- The extent to which adequate protections are afforded to human subjects.
- The extent to which the proposal is in compliance with the Department of Health and Human Services (HHS) regulations for protection of human subjects (45 CFR Part 46). See the instructions in the Grants.gov Application Guide SF424 (R&R), Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Appendix B.
- The extent to which the applicant discusses plans to seek Institutional Review Board (IRB) approval (IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects).

CRITERION 4: IMPACT (10 points) (Related Program Narrative Section: Specific Aims, Significance, and Dissemination Plan)

The extent and effectiveness of plans for dissemination of project results and/or the extent to which project results may be regional or national in scope and/or degree to which the project activities are replicable. The likelihood for the project to exert a sustained, powerful influence on the research field(s) involved.

- The extent to which there is an effective publication and dissemination plan.
- The degree to which the applicant has a sound plan for how they will meet the expectation to produce the expected minimum number of peer-reviewed publications (i.e., 3 publications expected for each **R40 Extramural MCH Research** study and 2 publications expected for each **R40 SDAS** study).
- The extent to which the problem addressed by the proposed research is unique to a community or region or is one of national proportion.
- The extent to which the findings will be generalizable and of regional or national significance.
- The extent to which the number of mothers or children affected by the problem or who will benefit from the research is significant.

- The degree to which the proposed project will advance the research field by having a sustained and powerful influence.
- If the investigators are past MCH Research Program grantees, the extent to which they have demonstrated publication success from their previous grant(s).

CRITERION 5: RESOURCES/CAPABILITIES (10 points) (Related Program Narrative Section: Preliminary Studies, Environment, Staffing Plan in Budget Narrative, Biographical Sketches)

The extent to which project personnel are qualified by training and/or experience to implement and carry out the research project. The capabilities of the applicant organization, and quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed research project.

- The extent to which the Principal Investigator (PI), collaborators, staff, and other researchers are well qualified by training and/or expertise to conduct the research.
- If Early Stage Investigators or New Investigators, the appropriateness of their experience and training. If established, the degree to which they have demonstrated an ongoing record of accomplishments that have advanced their field(s).
- The extent to which the scientific environment in which the work will be done contributes to the probability of project success.
- The adequacy of the institutional support, equipment, and other physical resources available to the PI and co-investigators for the proposed project.
- The extent to which the project will benefit from unique features of the scientific environment, subject populations, or collaborative arrangements.
- The extent to which all key personnel have indicated other current and pending support in their biographical sketches. (Note: A current PI of an MCH Research grant can serve for no more than 10% time on a new proposal).
- The degree to which the applicant provides assurance that the research team will conduct and complete the study as proposed. (It is expected that funded projects will demonstrate ongoing progress and completion as proposed and approved).
- The degree to which the PI and other key personnel demonstrate current and/or past success in publishing the findings of their research. In particular, if investigators are past MCH Research Program grantees, the degree to which they demonstrate publication success from their previous grant(s).

CRITERION 6: SUPPORT REQUESTED (10 points) (Related Program Narrative Section and Budget Section: Financing, Budget Justification)

The reasonableness of the proposed budget in relation to the objectives, the complexity of the research activities, and the anticipated results.

- The extent to which costs as outlined in the budget and required resources sections are reasonable given the scope of work.
- The extent to which budget line items are well described and justified in the budget justification.
- The extent to which time allocated by key personnel is realistic and appropriate to achieve project objectives.
- The extent to which the application addresses other current and pending support for the current project.

2. Review and Selection Process

The Division of Independent Review is responsible for managing objective reviews within HRSA. Applications competing for Federal funds receive an objective and independent review performed by a committee of experts qualified by training and experience in particular fields or disciplines related to the program being reviewed. In selecting review committee members, other factors in addition to training and experience may be considered to improve the balance of the committee, e.g., geographic distribution. Each reviewer is screened to avoid conflicts of interest and is responsible for providing an objective, unbiased evaluation based on the review criteria noted above. The committee provides expert advice on the merits of each application to program officials responsible for final selections for award.

Applications that pass the initial HRSA eligibility screening will be reviewed and rated by a panel based on the program elements and review criteria presented in relevant sections of this funding opportunity announcement. The review criteria are designed to enable the review panel to assess the quality of a proposed project and determine the likelihood of its success. The criteria are closely related to each other and are considered as a whole in judging the overall quality of an application.

3. Anticipated Announcement and Award Dates

It is anticipated that awards will be announced prior to the start date of February 1, 2013.

VI. Award Administration Information

1. Award Notices

Each applicant will receive written notification of the outcome of the objective review process, including a summary of the expert committee's assessment of the application's strengths and weaknesses, and whether the application was selected for funding. Applicants who are selected for funding may be required to respond in a satisfactory manner to Conditions placed on their application before funding can proceed. Letters of notification do not provide authorization to begin performance.

The Notice of Award (NoA) sets forth the amount of funds granted, the terms and conditions of the award, the effective date of the award, the budget period for which initial support will be given, the non-Federal share to be provided (if applicable), and the total project period for which support is contemplated. Signed by the Grants Management Officer, it is sent to the applicant's Authorized Organization Representative, and reflects the only authorizing document. It will be sent prior to the start date of February 1, 2013.

2. Administrative and National Policy Requirements

Successful applicants must comply with the administrative requirements outlined in 45 CFR Part 74 <u>Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Nonprofit Organizations, and Commercial Organizations or 45 CFR</u>

Part 92 <u>Uniform Administrative Requirements For Grants And Cooperative Agreements to State, Local, and Tribal Governments</u>, as appropriate.

HRSA grant and cooperative agreement awards are subject to the requirements of the HHS Grants Policy Statement (HHS GPS) that are applicable based on recipient type and purpose of award. This includes any requirements in Parts I and II of the HHS GPS that apply to the award. The HHS GPS is available at http://www.hrsa.gov/grants/. The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary (as specified in the NoA).

Non-Discrimination Requirements

To serve persons most in need and to comply with Federal law, services must be widely accessible. Services must not discriminate on the basis of age, disability, sex, race, color, national origin or religion. The HHS Office for Civil Rights provides guidance to grant and cooperative agreement recipients on complying with civil rights laws that prohibit discrimination on these bases. Please see http://www.hhs.gov/ocr/civilrights/understanding/index.html. HHS also provides specific guidance for recipients on meeting their legal obligation under Title VI of the Civil Rights Act of 1964, which prohibits discrimination on the basis of race, color or national origin in programs and activities that receive Federal financial assistance (P.L. 88-352, as amended and 45 CFR Part 80). In some instances a recipient's failure to provide language assistance services may have the effect of discriminating against persons on the basis of their national origin. Please see http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html to learn more about the Title VI requirement for grant and cooperative agreement recipients to take reasonable steps to provide meaningful access to their programs and activities by persons with limited English proficiency.

Human Subjects Protection

Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If research involving human subjects is anticipated, grantees must meet the requirements of the HHS regulations to protect human subjects from research risks as specified in the Code of Federal Regulations, Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (45 CFR 46), available online at www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

Financial Conflict of Interest

HHS requires awardees and investigators to comply with the requirements of 42 CFR part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." A Final Rule amending this PHS regulation (and the companion regulation at 45 CFR part 94, "Responsible Prospective Contractors," imposing similar requirements for research contracts) was published on August 25, 2011 in the Federal Register (http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf). An Institution applying for or receiving PHS funding from a grant or cooperative agreement that is covered by the rule must be in full compliance with all of the revised regulatory requirements no later than August 24, 2012, and immediately upon making its institutional Financial Conflict of Interest (FCOI) policy publicly accessible as described in the regulation.

Trafficking in Persons

Awards issued under this funding opportunity announcement are subject to the requirements of Section 106 (g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104). For the full text of the award term, go to http://www.hrsa.gov/grants/trafficking.html.

Smoke-Free Workplace

The Public Health Service strongly encourages all award recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. Further, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

Cultural and Linguistic Competence

HRSA programs serve culturally and linguistically diverse communities and multiple cultures. Although race and ethnicity are often thought to be dominant elements of culture, HRSA funded programs embrace a broader definition to incorporate diversity within specific cultural groups including but not limited to cultural uniqueness within Native American populations, Native Hawaiian, Pacific Islanders, and other ethnic groups, language, gender, socio-economic status, sexual orientation and gender identity, physical and mental capacity, age, religion, housing status, and regional differences. Organizational behaviors, practices, attitudes, and policies across all HRSA-supported entities respect and respond to the cultural diversity of communities, clients and students served. HRSA is committed to ensuring access to quality health care for all. Quality care means access to services, information, materials delivered by competent providers in a manner that factors in the language needs, cultural richness, and diversity of populations served. Quality also means that, where appropriate, data collection instruments used should adhere to culturally competent and linguistically appropriate norms. For additional information and guidance, refer to the National Standards for Culturally and Linguistically Appropriate Services in Health Care (CLAS) published by HHS and available online at http://minorityhealth.hhs.gov/templates/browse.aspx?lvl=2&lvlID=15. Additional cultural competency and health literacy tools, resources and definitions are available online at http://www.hrsa.gov/culturalcompetence and http://www.hrsa.gov/healthliteracy.

Healthy People 2020

Healthy People 2020 is a national initiative led by HHS that sets priorities for all HRSA programs. The initiative has four overarching goals: (1) attain high-quality, longer lives free of preventable disease, disability, injury, and premature death; (2) achieve health equity, eliminate disparities, and improve the health of all groups; (3) create social and physical environments that promote good health for all; and (4) promote quality of life, healthy development, and healthy behaviors across all life stages. The program consists of over 40 topic areas, containing measurable objectives. HRSA has actively participated in the work groups of all the topic areas and is committed to the achievement of the Healthy People 2020 goals. More information about Healthy People 2020 may be found online at http://www.healthypeople.gov/.

National HIV/AIDS Strategy (NHAS)

The National HIV/AIDS Strategy (NHAS) has three primary goals: (1) reducing the number of people who become infected with HIV; (2) increasing access to care and optimizing health outcomes for people living with HIV; and (3) reducing HIV-related health disparities. The NHAS states that more must be done to ensure that new prevention methods are identified and that prevention resources are more strategically deployed. Further, the NHAS recognizes the importance of early entrance into care for people living with HIV to protect their health and reduce their potential of transmitting the virus to others. HIV disproportionately affects people

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who have less access to prevention, care and treatment services and, as a result, often have poorer health outcomes. Therefore, the NHAS advocates adopting community-level approaches to identify people who are HIV-positive but do not know their serostatus and reduce stigma and discrimination against people living with HIV.

To the extent possible, program activities should strive to support the three primary goals of the NHAS. As encouraged by the NHAS, programs should seek opportunities to increase collaboration, efficiency, and innovation in the development of program activities to ensure success of the NHAS. Programs providing direct services should comply with federally-approved guidelines for HIV Prevention and Treatment (see http://www.aidsinfo.nih.gov/Guidelines/Default.aspx as a reliable source for current guidelines). More information can also be found at http://www.whitehouse.gov/administration/eop/onap/nhas.

Health IT

Health information technology (Health IT) provides the basis for improving the overall quality, safety and efficiency of the health delivery system. HRSA endorses the widespread and consistent use of health IT, which is the most promising tool for making health care services more accessible, efficient and cost effective for all Americans.

Related Health IT Resources:

- Health Information Technology (HHS)
- What is Health Care Quality and Who Decides? (AHRQ)

Product and Data Rights

The grantees acknowledge that the MCHB has uncontested access to any and all data generated under these grants, acknowledge and agree that in accordance with 45 CFR 74.36, the HHS Grants Policy Statement provides that if any copyrightable material (e.g., audiovisuals, software, publications, curricula and training materials, etc.) is developed under this grant (by the Awardee or contractor) HHS shall have a royalty-free nonexclusive and irrevocable right to reproduce, publish or otherwise use, and authorize others to use, the material for Federal purposes such as furthering the objective of the Maternal and Child Health (MCH) Research Program (e.g., to make it available in government-sponsored databases for use by other researchers). All contracts or other arrangements entered into by the grantees for purpose of developing or procuring such material shall specifically reference and reserve the rights of HHS with respect to the material. The grantee shall provide a master electronic or digital file and four final reproducible copies of all such copyrightable material upon the request of the MCHB.

3. Reporting

The successful applicant under this funding opportunity announcement must comply with the following reporting and review activities:

a. Audit Requirements

Comply with audit requirements of Office of Management and Budget (OMB) Circular A-133. Information on the scope, frequency, and other aspects of the audits can be found on the Internet at http://www.whitehouse.gov/omb/circulars_default.

b. Payment Management Requirements

Submit a quarterly electronic Federal Financial Report (FFR) Cash Transaction Report via the Payment Management System. The report identifies cash expenditures against the authorized funds for the grant or cooperative agreement. The FFR Cash Transaction Reports must be filed within 30 days of the end of each calendar quarter. Failure to submit the report may result in the inability to access award funds. Go to http://www.dpm.psc.gov for additional information.

c. Status Reports

- 1) **Federal Financial Report**. The Federal Financial Report (SF-425) is required according to the following schedule: http://www.hrsa.gov/grants/manage/technicalassistance/federalfinancialreport/ffrschedule.pdf. The report is an accounting of expenditures under the project that year. Financial reports must be submitted electronically through EHB. More specific information will be included in the NoA.
- 2) **Progress Report**(s). (**Not Applicable to R40 SDAS**) The awardee must submit a progress report to HRSA on an annual basis. For R40 Extramural MCH Research, submit an **Annual Continuation Application/Progress Report.** Submission and HRSA approval of grantee Progress Report(s) triggers the budget period renewal and release of subsequent year funds. This report has two parts. The first part demonstrates grantee progress on program-specific goals. The second part collects core performance measurement data including performance measurement data to measure the progress and impact of the project. Further information will be provided in the NoA.
- 3) **Mid-Project Progress Report(s).** For **R40 Extramural MCH Research**, submit a **Mid-Project Progress Report**. For **R40 SDAS**, submit a **Mid-Year Progress Report**. Further information will be provided in the NoA.
- 4) **Final Report.** A final report is due within 90 days after the project period ends. The final report collects program-specific goals and progress on strategies; core performance measurement data; impact of the overall project; the degree to which the grantee achieved the mission, goal and strategies outlined in the program; grantee objectives and accomplishments; barriers encountered; and responses to summary questions regarding the grantee's overall experiences over the entire project period. The final report must be submitted on-line by awardees in the Electronic Handbooks system at https://grants.hrsa.gov/webexternal/home.asp.
- 5) Tangible Personal Property Report. If applicable, the awardee must submit the Tangible Personal Property Report (SF-428) and any related forms. The report must be submitted within 90 days after the project period ends. Awardees are required to report all federally-owned property and acquired equipment with an acquisition cost of \$5,000 or more per unit. Tangible personal property means property of any kind, except real property, that has physical existence. It includes equipment and supplies. Property may be provided by HRSA or acquired by the recipient with award funds. Federally-owned property consists of items that were furnished by the Federal Government. Tangible personal property reports must be submitted electronically through EHB. More specific information will be included in the NoA.
- 6) **Performance Report(s)**. The Health Resources and Services Administration (HRSA) has modified its reporting requirements for SPRANS projects, CISS projects, and other

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grant programs administered by the Maternal and Child Health Bureau (MCHB) to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for Federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for States have also been established under the Block Grant provisions of Title V of the Social Security Act, the MCHB's authorizing legislation. Performance measures for other MCHB-funded grant programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect.

1. Performance Measures and Program Data

To prepare applicants for these reporting requirements, the designated performance measures for this program and other program data collection are presented in Appendix A of this funding opportunity announcement.

2. Performance Reporting

Successful applicants receiving grant funds will be required, within 120 days of the Notice of Award (NoA), to register in HRSA's Electronic Handbooks (EHBs) and electronically complete the program specific data forms that appear in the Appendix A of this funding opportunity announcement. This requirement entails the provision of budget breakdowns in the financial forms based on the grant award amount, the project abstract and other grant summary data as well as providing objectives for the performance measures.

Performance reporting is conducted for each grant year of the project period. Grantees will be required, within 120 days of the NoA, to enter HRSA's EHBs and complete the program specific forms. This requirement includes providing expenditure data, finalizing the abstract and grant summary data as well as finalizing indicators/scores for the performance measures.

3. Project Period End Performance Reporting

Successful applicants receiving grant funding will be required, within 90 days from the end of the project period, to electronically complete the program specific data forms that appear in the Appendix A of this funding opportunity announcement. The requirement includes providing expenditure data for the final year of the project period, the project abstract and grant summary data as well as final indicators/scores for the performance measures.

d. Transparency Act Reporting Requirements

New awards ("Type 1") issued under this funding opportunity announcement are subject to the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) of 2006 (Pub. L. 109–282), as amended by section 6202 of Public Law 110–252, and implemented by 2 CFR Part 170. Grant and cooperative agreement recipients must report information for each first-tier subaward of \$25,000 or more in Federal funds and executive total compensation for the recipient's and subrecipient's five most highly compensated executives as outlined in Appendix A to 2 CFR Part 170 (FFATA details are available online at http://www.hrsa.gov/grants/ffata.html). Competing continuation awardees, etc. may be subject to this requirement and will be so notified in the NoA.

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VII. Agency Contacts

Applicants may obtain additional information regarding business, administrative, or fiscal issues related to this funding opportunity announcement by contacting:

Janene P. Dyson Grants Management Specialist Maternal Child & Health Systems Branch HRSA, Division of Grants Mgmt. Operations 5600 Fishers Lane, Room 11-103 Rockville, MD 20857

Telephone: (301) 443-8325

Fax: (301) 594-4073 E-mail: <u>JDyson@hrsa.gov</u>

Additional information related to the overall program issues and/or technical assistance regarding this funding announcement may be obtained by contacting:

Robin Harwood and Hae Young Park Program Officers, Division of Research Attn: R40 MCH Research Program Maternal and Child Health Bureau, HRSA Parklawn Building, Room 18A-55 5600 Fishers Lane Rockville, MD 20857 Telephone: (301) 443-2207

Fax: (301) 443-4842

Email: rharwood@hrsa.gov; hpark@hrsa.gov

Applicants may need assistance when working online to submit their application forms electronically. Applicants should always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, seven days a week, excluding Federal holidays at:

Grants.gov Contact Center Telephone: 1-800-518-4726 E-mail: support@grants.gov iPortal: http://grants.gov/iportal

Successful applicants/awardees may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Call Center, Monday-Friday, 9:00 a.m. to 5:30 p.m. ET:

HRSA Contact Center Telephone: (877) 464-4772 TTY: (877) 897-9910

E-mail: CallCenter@HRSA.GOV

VIII. Other Information

Bright Futures

http://www.brightfutures.aap.org/

Healthy People 2020

http://www.healthypeople.gov/2020/

Human Subjects Assurances

http://www.hhs.gov/ohrp

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Inclusion of children

http://grants.nih.gov/grants/funding/children/children.htm

Institute of Medicine

http://www.iom.edu

Making Websites Accessible: Section 508 of the Rehabilitation Act

http://www.section508.gov/

MCH Training Web Site

http://www.mchb.hrsa.gov/training

National Center for Cultural Competence

http://nccc.georgetown.edu/

National Center for Medical Home Implementation

http://www.medicalhomeinfo.org/

IX. Tips for Writing a Strong Application

HRSA has designed a technical assistance webpage to assist applicants in preparing applications. Resources include help with system registration, finding and applying for funding opportunities, writing strong applications, understanding the review process, and many other topics which applicants will find relevant. The website can be accessed online at:

http://www.hrsa.gov/grants/apply/index.html.

In addition, a concise resource offering tips for writing proposals for HHS grants and cooperative agreements can be accessed online at:

http://dhhs.gov/asfr/ogapa/grantinformation/apptips.html

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Appendix A: MCHB Administrative Forms and Performance Measures

To prepare successful applicants for their future performance reporting requirements, the Administrative Forms and Performance Measures assigned to this MCHB program are presented below.

- Form 1, MCHB Project Budget Details
- Form 2, Project Funding Profile
- Form 4, Project Budget and Expenditures by Types of Services (Note, funds for the R40 MCH Research program would fit under "Infrastructure Building Services")
- Form 7, Discretionary Grant Project Summary Data
- Form 8, Abstract for Research Projects
- Performance Measure 03, The percentage of MCHB-funded projects submitting and publishing findings in peer-reviewed journals.
- Performance Measure 10, The degree to which MCHB-funded programs have incorporated cultural and linguistic competence elements into their policies, guidelines, contracts and training
- Products, Publications and Submissions Data Form

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FORM 1

MCHB PROJECT BUDGET DETAILS FOR FY _____

1.	MCHB GRANT AWARD AMOUNT		\$
2.	UNOBLIGATED BALANCE		\$
3.	MATCHING FUNDS		\$
	(Required: Yes [] No [] If yes, amount)		
	A. Local funds	\$	
	B. State funds	\$	
	C. Program Income	\$	
	D. Applicant/Grantee Funds	\$	
	E. Other funds:	\$	
4.	OTHER PROJECT FUNDS (Not included in 3 above)	Ψ	
••	A. Local funds	\$	Ψ
	B. State funds	\$	
	C. Program Income (Clinical or Other)	\$	
	D. Applicant/Grantee Funds (includes in-kind)	\$	
	E. Other funds (including private sector, e.g., Foundations)	\$	
5.	TOTAL PROJECT FUNDS (Total lines 1 through 4)	Ψ	
6.	FEDERAL COLLABORATIVE FUNDS		\$
٠.	(Source(s) of additional Federal funds contributing to the project)		Ψ
	A. Other MCHB Funds (Do not repeat grant funds from Line 1)		
		Ф	
	1) Special Projects of Regional and National Significance (SPRANS)	\$	
	2) Community Integrated Service Systems (CISS)	\$	
	3) State Systems Development Initiative (SSDI)	\$	
	4) Healthy Start	\$	
	5) Emergency Medical Services for Children (EMSC)	\$	
	6) Traumatic Brain Injury	\$	
	7) State Title V Block Grant	\$	
	8) Other:	\$	
	9) Other:	\$ \$	
	10) Other: B. Other HRSA Funds	<u> </u>	
	1) HIV/AIDS	\$	
	2) Primary Care	\$	
	3) Health Professions	\$	
	4) Other:	\$	
	5) Other:	\$	
	6) Other:	<u>Ф</u>	
	C. Other Federal Funds	Ψ	
	1) Center for Medicare and Medicaid Services (CMS)	\$	
	2) Supplemental Security Income (SSI)	\$	
	3) Agriculture (WIC/other)	\$	
	4) Administration for Children and Families (ACF)	\$	
	5) Centers for Disease Control and Prevention (CDC)	\$	
	6) Substance Abuse and Mental Health Services Administration (SAMHSA)	\$	
	7) National Institutes of Health (NIH)	\$	
	8) Education	\$	
	9) Bioterrorism	Ψ	
	10) Other:	\$	
	11) Other:	\$	
	12) Other	\$	
7	TOTAL COLLABODATIVE FEDERAL FUNDS	<u> </u>	

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INSTRUCTIONS FOR COMPLETION OF FORM 1 MCH BUDGET DETAILS FOR FY ____

- Line 1. Enter the amount of the Federal MCHB grant award for this project.
- Line 2. Enter the amount of carryover (e.g., unobligated balance) from the previous year's award, if any. New awards do not enter data in this field, since new awards will not have a carryover balance.
- Line 3. If matching funds are required for this grant program list the amounts by source on lines 3A through 3E as appropriate. Where appropriate, include the dollar value of in-kind contributions.
- Line 4. Enter the amount of other funds received for the project, by source on Lines 4A through 4E, specifying amounts from each source. Also include the dollar value of in-kind contributions.
- Line 5. Displays the sum of lines 1 through 4.
- Line 6. Enter the amount of other Federal funds received on the appropriate lines (A.1 through C.12) **other** than the MCHB grant award for the project. Such funds would include those from other Departments, other components of the Department of Health and Human Services, or other MCHB grants or contracts.
 - Line 6C.1. Enter only project funds from the Center for Medicare and Medicaid Services. Exclude Medicaid reimbursement, which is considered Program Income and should be included on Line 3C or 4C.
 - If lines 6A.8-10, 6B.4-6, or 6C.10-12 are utilized, specify the source(s) of the funds in the order of the amount provided, starting with the source of the most funds.
- Line 7. Displays the sum of lines in 6A.1 through 6C.12.

FORM 2 PROJECT FUNDING PROFILE

	FY		FY		FY		FY		FY	
	Budgeted	Expended	Budgeted	Expended	Budgeted	Expended	Budgeted	Expended	Budgeted	Expended
1 MCHB Grant Award Amount Line 1, Form 2	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$
2 <u>Unobligated</u> <u>Balance</u> <i>Line 2, Form 2</i>	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$
3 Matching Funds (If required) Line 3, Form 2	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$
4 Other Project Funds Line 4, Form 2	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$
5 Total Project Funds Line 5, Form 2	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$
6 Total Federal Collaborative Funds Line 7, Form 2	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$

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INSTRUCTIONS FOR THE COMPLETION OF FORM 2 PROJECT FUNDING PROFILE

Instructions:

Complete all required data cells. If an actual number is not available, use an estimate. Explain all estimates in a note.

The form is intended to provide funding data at a glance on the estimated budgeted amounts and actual expended amounts of an MCH project.

For each fiscal year, the data in the columns labeled Budgeted on this form are to contain the same figures that appear on the Application Face Sheet (for a non-competing continuation) or the Notice of Grant Award (for a performance report). The lines under the columns labeled Expended are to contain the actual amounts expended for each grant year that has been completed.

FORM 4 PROJECT BUDGET AND EXPENDITURES By Types of Services

		FY		FY	FY		
	TYPES OF SERVICES	Budgeted	Expended	Budgeted	Expended		
I.	Direct Health Care Services (Basic Health Services and Health Services for CSHCN.)	\$	\$	\$	\$		
II.	Enabling Services (Transportation, Translation, Outreach, Respite Care, Health Education, Family Support Services, Purchase of Health Insurance, Case Management, and Coordination with Medicaid, WIC and Education.)	\$	\$	\$	\$		
ш.	Population-Based Services (Newborn Screening, Lead Screening, Immunization, Sudden Infant Death Syndrome Counseling, Oral Health, Injury Prevention, Nutrition, and Outreach/Public Education.)	\$	\$	\$	\$		
IV.	Infrastructure Building Services (Needs Assessment, Evaluation, Planning, Policy Development, Coordination, Quality Assurance, Standards Development, Monitoring, Training, Applied Research, Systems of Care, and Information Systems.)	\$	\$	\$	\$		
v.	TOTAL	\$	\$	\$	\$		

EXPIRATION DATE: 10/31/2012

INSTRUCTIONS FOR THE COMPLETION OF FORM 4 PROJECT BUDGET AND EXPENDITURES BY TYPES OF SERVICES

Complete all required data cells for all years of the g rant. If an actual number is not available, make an estimate. Please explain all estimates in a note. Administrative dollars should be allocated to the appropriate level(s) of the pyramid on lines I, II, II or IV. If an estimate of administrative funds use is necessary, one method would be to allocate those dollars to Lines I, II, III and IV at the same percentage as program dollars are allocated to Lines I through IV.

Note: Lines I, II and II are for projects providing services. If grant funds are used to build the infrastructure for direct care delivery, enabling or population-based services, these amounts should be reported in Line IV (i.e., building data collection capacity for newborn hearing screening).

Line I Direct Health Care Services - enter the budgeted and expended amounts for the appropriate fiscal year completed and budget estimates only for all other years.

> Direct Health Care Services are those services generally delivered one-on-one between a health professional and a patient in an office, clinic or emergency room which may include primary care physicians, registered dietitians, public health or visiting nurses, nurses certified for obstetric and pediatric primary care, medical social workers, nutritionists, dentists, subspecialty physicians who serve children with special health care needs, audiologists, occupational therapists, physical therapists, speech and language therapists, specialty registered dietitians. Basic services include what most consider ordinary medical care, inpatient and outpatient medical services, allied health services, drugs, laboratory testing, x-ray services, dental care, and pharmaceutical products and services. State Title V programs support - by directly operating programs or by funding local providers - services such as prenatal care, child health including immunizations and treatment or referrals, school health and family planning. For CSHCN, these services include specialty and sub-specialty care for those with HIV/AIDS, hemophilia, birth defects, chronic illness, and other conditions requiring sophisticated technology, access to highly trained specialists, or an array of services not generally available in most communities.

Line II Enabling Services - enter the budgeted and expended amounts for the appropriate fiscal year completed and budget estimates only for all other years.

> **Enabling Services** allow or provide for access to and the derivation of benefits from, the array of basic health care services and include such things as transportation, translation services, outreach, respite care, health education, family support services, purchase of health insurance, case management, coordination of with Medicaid, WIC and educations. These services are especially required for the low income, disadvantaged, geographically or culturally isolated, and those with special and complicated health needs. For many of these individuals, the enabling services are essential - for without them access is not possible. Enabling services most commonly provided by agencies for CSHCN include transportation, care coordination, translation services, home visiting, and family outreach. Family support activities include parent support groups, family training workshops, advocacy, nutrition and social work.

Line III Population-Based Services - enter the budgeted and expended amounts for the appropriate fiscal year completed and budget estimates only for all other years.

> **Population Based Services** are preventive interventions and personal health services, developed and available for the entire MCH population of the State rather than for individuals in a one-on-one situation. Disease prevention, health promotion, and statewide outreach are major components. Common among these services are newborn screening, lead screening, immunization, Sudden Infant Death Syndrome counseling, oral health, injury prevention, nutrition and outreach/public education. These services are generally available whether the

mother or child receives care in the private or public system, in a rural clinic or an HMO, and whether insured or not.

Line IV <u>Infrastructure Building Services</u> - enter the budgeted and expended amounts for the appropriate fiscal year completed and budget estimates only for all other years.

Infrastructure Building Services are the base of the MCH pyramid of health services and form its foundation. They are activities directed at improving and maintaining the health status of all women and children by providing support for development and maintenance of comprehensive health services systems and resources including development and maintenance of health services standards/guidelines, training, data and planning systems. Examples include needs assessment, evaluation, planning, policy development, coordination, quality assurance, standards development, monitoring, training, applied research, information systems and systems of care. In the development of systems of care it should be assured that the systems are family centered, community based and culturally competent.

Line V Total – Displays the total amounts for each column, budgeted for each year and expended for each year completed.

FORM 7 DISCRETIONARY GRANT PROJECT SUMMARY DATA

1.	Project Service Focus [] Urban/Central City [] Suburban [] Metropolitan Area (city & suburbs) [] Rural [] Frontier [] Border (US-Mexico)
2.	Project Scope [] Local [] Multi-county [] State-wide [] Regional [] National
3.	Grantee Organization Type [] State Agency [] Community Government Agency [] School District [] University/Institution of Higher Learning (Non-Hospital Based) [] Academic Medical Center [] Community-Based Non-Governmental Organization (Health Care) [] Community-Based Non-Governmental Organization (Non-Health Care) [] Professional Membership Organization (Individuals Constitute Its Membership) [] National Organization (Other Organizations Constitute Its Membership) [] National Organization (Non-Membership Based) [] Independent Research/Planning/Policy Organization [] Other
4.	Project Infrastructure Focus (from MCH Pyramid) if applicable [] Guidelines/Standards Development and Maintenance [] Policies and Programs Study and Analysis [] Synthesis of Data and Information [] Translation of Data and Information for Different Audiences [] Dissemination of Information and Resources [] Quality Assurance [] Technical Assistance [] Training [] Systems Development [] Other

5. Demographic Characteristics of Project Participants

Direct Health Care Services	Population-Based Services
Enabling Services	Infrastructure Building Services

	RACE (Indicate all that apply)								ETHNICITY			
	American Indian or Alaska Native	Asian	Black or African American	Native Hawaiian or Other Pacific Islander	White	More than One Race	Unrecorded	Total	Hispanic or Latino	Not Hispanic or Latino	Unrecorded	Total
Pregnant Women (All Ages) Infants <1				zstandel								
year Children												
Youth 1 to 25 years												
CSHCN Infants <1 year												
CSHCN Children and Youth 1 to 25 years												
Women 25+ years												
Men 25+ years												
TOTALS												

Clients' Primary Language(s)	
Resource/TA and Training Centers ONLY	
Answer all that apply.	
a. Characteristics of Primary Intended Audience(s)	
[] Policy Makers/Public Servants	
[] Consumers	
[] Providers/Professionals	
b. Number of Requests Received/Answered:	/
c. Number of Continuing Education credits provided:	
d. Number of Individuals/Participants Reached:	
e. Number of Organizations Assisted:	
f. Major Type of TA or Training Provided:	
[] continuing education courses,	
[] workshops,	
[] on-site assistance,	
[] distance learning classes	
[] other	

INSTRUCTIONS FOR THE COMPLETION OF FORM 7 PROJECT SUMMARY

Section 1 – Project Service Focus

Select all that apply

Section 2 – Project Scope

Choose the one that best applies to your project.

Section 3 – Grantee Organization Type

Choose the one that best applies to your organization.

Section 4 – Project Infrastructure Focus

If applicable, choose all that apply.

Section 5 – Demographic Characteristics of Project Participants

Indicate the service level for the grant program. Multiple selections may be made. Please fill in each of the cells as appropriate.

Direct Health Care Services are those services generally delivered one-on-one between a health professional and a patient in an office, clinic or emergency room which may include primary care physicians, registered dietitians, public health or visiting nurses, nurses certified for obstetric and pediatric primary care, medical social workers, nutritionists, dentists, sub-specialty physicians who serve children with special health care needs, audiologists, occupational therapists, physical therapists, speech and language therapists, specialty registered dietitians. Basic services include what most consider ordinary medical care, inpatient and outpatient medical services, allied health services, drugs, laboratory testing, x-ray services, dental care, and pharmaceutical products and services. State Title V programs support - by directly operating programs or by funding local providers - services such as prenatal care, child health including immunizations and treatment or referrals, school health and family planning. For CSHCN, these services include specialty and sub-specialty care for those with HIV/AIDS, hemophilia, birth defects, chronic illness, and other conditions requiring sophisticated technology, access to highly trained specialists, or an array of services not generally available in most communities.

Enabling Services allow or provide for access to and the derivation of benefits from, the array of basic health care services and include such things as transportation, translation services, outreach, respite care, health education, family support services, purchase of health insurance, case management, coordination of with Medicaid, WIC and educations. These services are especially required for the low income, disadvantaged, geographically or culturally isolated, and those with special and complicated health needs. For many of these individuals, the enabling services are essential - for without them access is not possible. Enabling services most commonly provided by agencies for CSHCN include transportation, care coordination, translation services, home visiting, and family outreach. Family support activities include parent support groups, family training workshops, advocacy, nutrition and social work.

Population Based Services are preventive interventions and personal health services, developed and available for the entire MCH population of the State rather than for individuals in a one-on-one situation. Disease prevention, health promotion, and statewide outreach are major components. Common among these services are newborn screening, lead screening, immunization, Sudden Infant Death Syndrome counseling, oral health, injury prevention, nutrition and outreach/public education. These services are generally available whether the mother or child receives care in the private or public system, in a rural clinic or an HMO, and whether insured or not.

Infrastructure Building Services are the base of the MCH pyramid of health services and form its foundation. They are activities directed at improving and maintaining the health status of all women and children by providing support for development and maintenance of comprehensive health services systems and resources including development and maintenance of health services standards/guidelines, training, data and planning systems. Examples include needs assessment, evaluation, planning, policy development, coordination, quality assurance, standards development, monitoring, training, applied research, information systems and systems of care. In the

development of systems of care it should be assured that the systems are family centered, community based and culturally competent.

Section 6 – Clients Primary Language(s)

Indicate which languages your clients speak as their primary language, other than English, for the data provided in Section 6. List up to three languages.

Section 7 – Resource/TA and Training Centers (Only)

Answer all that apply.

FORM 8

(For Research Projects ONLY) MATERNAL & CHILD HEALTH DISCRETIONARY GRANT PROJECT ABSTRACT FOR FY____

I.	PROJECT IDENTIFIER INFORMA	ATION
	1. Project Title:	
	2. Project Number:	
	3. Project Director:	
	4. Principle Investigator(s), Disciplin	e
II.	BUDGET	
	MCHB Grant Award	\$
	(Line 1, Form 2)	'
	2. Unobligated Balance	\$
	(Line 2, Form 2)	·
	3. Matching Funds (if applicable)	\$
	(Line 3, Form 2)	·
	4. Other Project Funds	\$
	(Line 4, Form 2)	
	5. Total Project Funds	\$
	(Line 5, Form 2)	
III.C	ARE EMPHASIS	
	[] Interventional	
	[] Non-interventional	
IV.PO	OPULATION FOCUS	
	[] Neonates	[] Pregnant Women
	[] Infants	[] Postpartum Women
	[] Toddlers	[] Parents/Mothers/Fathers
	[] Preschool Children	[] Adolescent Parents
	[] School-Aged Children	[] Grandparents
	[] Adolescents	[] Physicians
	[] Adolescents (Pregnancy Related)	[] Others
	[] Young Adults (>20)	
V. S	TUDY DESIGN	
	[] Experimental	
	[] Quasi-Experimental	
	[] Observational	
VI.	TIME DESIGN	
	[] Cross-sectional	
	[] Longitudinal	
	[] Mixed	
VII.	PRIORITY RESEARCH ISSUES AND From the Maternal and Child Health B	D QUESTIONS OF FOCUS Sureau (MCHB) Strategic Research Issues: Fiscal Years (FYs) 2004
	-2009.	

Primary area addressed by research:

Secondary area addressed by research:

VIII. ABSTRACT

IX.KEY WORDS

X. ANNOTATION

INSTRUCTIONS FOR THE COMPLETION OF FORM 8 MATERNAL & CHILD HEALTH RESEARCH PROJECT ABSTRACT

NOTE: All information provided should fit into the space provided in the form. Do not exceed the space provided.

Where information has previously been entered in forms 1 through 5, the information will automatically be transferred electronically to the appropriate place on this form.

Section I – Project Identifier Information

Project Title: Displays the title for the project.

Project Number: Displays the number assigned to the project (e.g., the grant number).

Project Director: Displays the name and degree(s) of the project director as listed on the grant

application.

Principal Investigator: Enter the name(s) and discipline(s) of the principal investigator(s).

Section II - Budget

The amounts for Lines 1 through 5 will be transferred from Form 1, Lines 1 through 5.

Section III – Care Emphasis

Indicate whether the study is interventional or non-interventional.

Section IV – Population Focus

Indicate which population(s) is the focus of the study. Check all that apply.

Section V – Study Design

Indicate which type of design the study uses.

Section VI - Time Design

Indicate which type of design the study uses.

Section VII – Priority Research Issues and Questions of Focus (DO NOT EXCEED THE SPACE PROVIDED)

Provide a brief statement of the primary and secondary (if applicable) areas to be addressed by the research. The topic(s) should be from those listed in the *Maternal and Child Health Bureau (MCHB) Strategic Research Issues: Fiscal Years (FYs)* 2004 – 2009).

Section VIII - Abstract

Section IX - - Key Words

Provide up to 10 key words to describe the project, including populations served. A list of key words used to classify active projects is included. Choose keywords from this list when describing your project.

Section X – Annotation

Provide a three- to five-sentence description of your project that identifies the project's purpose, the needs and problems, which are addressed, the goals and objectives of the project, the activities, which will be used to attain the goals, and the materials, which will be developed.

03 PERFORMANCE MEASURE

Goal 1: Provide National Leadership for MCHB (Strengthen the MCH knowledge base and support scholarship within the MCH community)

Level: Grantee

Category: Information Dissemination

The percentage of MCHB-funded projects submitting and publishing findings in peer-reviewed journals.

GOAL

To increase the number of MCHB-funded research projects that publish in peer-reviewed journals.

MEASURE

The percent of MCHB-funded projects submitting articles and publishing findings in peer-reviewed journals.

DEFINITION

Numerator: Number of projects (current and completed within the past three years) that have submitted articles for review by refereed journals.

Denominator: Total number of current projects and projects that have been completed within the past three years.

And

Numerator: Number of projects (current and completed within the past 3 years) that have published articles in peer reviewed journals

Denominator: Total number of current projects and projects that have been completed within the past three years.

Units: 100 Text: Percent

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HEALTHY PEOPLE 2010 OBJECTIVE

Related to Goal 1: Improve access to comprehensive, high-quality health care services (Objectives 1.1-1.16).

DATA SOURCE(S) AND ISSUES

Attached data collection form will be sent annually to grantees during their funding period and three years after the funding period ends.

Some preliminary information may be gathered from mandated project final reports

SIGNIFICANCE

To be useful, the latest evidence-based, scientific knowledge must reach professionals who are delivering services, developing programs and making policy. Peer reviewed journals are considered one of the best methods for distributing new knowledge because of their wide circulation and rigorous standard of review.

DATA COLLECTION FORM FOR DETAIL SHEET #03

Please use the space provided for notes to detail the data source and year of data used.
Number of articles submitted for review by refereed journals but not yet published in this reporting year
Number of articles published in peer-reviewed journals this reporting year

NOTES/COMMENTS:

10 PERFORMANCE MEASURE

Goal 2: Eliminate Health Barriers & Disparities (Develop and promote health services and systems of care designed to eliminate disparities and barriers across MCH populations)

Level: Grantee

The degree to which MCHB-funded programs have incorporated cultural and linguistic competence elements into their policies, guidelines, contracts and training.

Cotogowy Cultural Co

Category: Cultural Competence

GOAL

To increase the number of MCHB-funded programs that have integrated cultural and linguistic competence into their policies, guidelines, contracts and training.

MEASURE

The degree to which MCHB-funded programs have incorporated cultural and linguistic competence elements into their policies, guidelines, contracts and training.

DEFINITION

Attached is a checklist of 15 elements that demonstrate cultural and linguistic competency. Please check the degree to which the elements have been implemented. The answer scale for the entire measure is 0-45. Please keep the completed checklist attached.

Cultural and linguistic competence is a set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals that enables effective work in crosscultural situations. 'Culture' refers to integrated patterns of human behavior that include the language, thoughts, communications, actions, customs, beliefs, values, and institutions of racial, ethnic, religious, or social groups. 'Competence' implies having the capacity to function effectively as an individual and an organization within the context of the cultural beliefs, behaviors, and needs presented by consumers and their communities. (Adapted from Cross, 1989; sited from DHHS Office of Minority Healthhttp://minorityhealth.hhs.gov/templates/browse.as px?lvl=2&lvlid=11)

Linguistic competence is the capacity of an organization and its personnel to communicate effectively, and convey information in a manner that is easily understood by diverse audiences including persons of limited English proficiency, those who have low literacy skills or are not literate, and individuals with disabilities. Linguistic competency requires organizational and provider capacity to respond effectively to the health literacy needs of populations served. The organization must have policy, structures,

practices, procedures, and dedicated resources to support this capacity. (Goode, T. and W. Jones, 2004. National Center for Cultural Competence; http://www.nccccurricula.info/linguisticcompetencee.html.)

Cultural and linguistic competency is a process that occurs along a developmental continuum. A culturally and linguistically competent program is characterized by elements including the following: written strategies for advancing cultural competence; cultural and linguistic competency policies and practices; cultural and linguistic competence knowledge and skills building efforts; research data on populations served according to racial, ethnic, and linguistic groupings; participation of community and family members of diverse cultures in all aspects of the program: faculty and other instructors are racially and ethnically diverse; faculty and staff participate in professional development activities related to cultural and linguistic competence; and periodic assessment of trainees' progress in developing cultural and linguistic competence.

HEALTHY PEOPLE 2010 OBJECTIVE

Related to the following HP2010 Objectives:

16.23: Increase the proportion of States and jurisdictions that have service systems for children with or at risk for chronic and disabling conditions as required by Public Law 101-239.

23.9: (Developmental) Increase the proportion of schools for public health workers that integrate into their curricula specific content to develop competency in the essential public health services.

23.11: (Developmental) Increase the proportion of State and local public health agencies that meet national performance standards for essential public health services.

23.15: (Developmental) Increase the proportion of Federal, Tribal, State, and local jurisdictions that review and evaluate the extent to which their statutes, ordinances, and bylaws assure the delivery of essential public health services.

DATA SOURCE(S) AND ISSUES

Attached data collection form is to be completed by grantees.

There is no existing national data source to measure the extent to which MCHB supported programs have incorporated cultural competence elements into their policies, guidelines, contracts and training.

SIGNIFICANCE

Over the last decade, researchers and policymakers

have emphasized the central influence of cultural values and cultural/linguistic barriers: health seeking behavior, access to care, and racial and ethnic disparities. In accordance with these concerns, cultural competence objectives have been: (1) incorporated into the MCHB strategic plan; and (2) in guidance materials related to the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), which is the legislative mandate that health programs supported by MCHB Children with Special Health Care Needs (CSHCN) provide and promote family centered, community-based, coordinated care.

DATA COLLECTION FORM FOR DETAIL SHEET #10

Using a scale of 0-3, please rate the degree to which your grant program has incorporated the following cultural/linguistic competence elements into your policies, guidelines, contracts and training.

Please use the space provided for notes to describe activities related to each element, detail data sources and year of data used to develop score, clarify any reasons for score, and or explain the applicability of elements to program.

0	1	2	3	Element
				1. Strategies for advancing cultural and linguistic competency are integrated into your
				program's written plan(s) (e.g., grant application, recruiting plan, placement
				procedures, monitoring and evaluation plan, human resources, formal agreements,
				etc.).
				2. There are structures, resources, and practices within your program to advance and
				sustain cultural and linguistic competency.
				3. Cultural and linguistic competence knowledge and skills building are included in
				training aspects of your program.
				4. Research or program information gathering includes the collection and analysis of
				data on populations served according to racial, ethnic, and linguistic groupings, where
				appropriate.
				5. Community and family members from diverse cultural groups are partners in
				planning your program.
				6. Community and family members from diverse cultural groups are partners in the
				delivery_of your program.
				7. Community and family members from diverse cultural groups are partners in
				evaluation of your program.
				8. Staff and faculty reflect cultural and linguistic diversity of the significant populations
				served.
				9. Staff and faculty participate in professional development activities to promote their
				cultural and linguistic competence.
				10. A process is in place to assess the progress of your program participants in developing
				cultural and linguistic competence.

\sim	T .	7 /
		Met

- 1 = Partially Met
- 2 = Mostly Met
- 3 = Completely Met

Total	the ni	imhers	in the	boxes	possible	0 - 30 s	core)	

NOTES/COMMENTS:

Products, Publications and Submissions Data Collection Form

Part 1

Instructions: Please list the number of products, publications and submissions addressing maternal and child health that have been published or produced by your staff during the reporting period (counting the original completed product or publication developed, not each time it is disseminated or presented). Products and Publications include the following types:

Туре	Number
Peer-reviewed publications in scholarly journals – published (including peer-reviewed journal commentaries or supplements)	
Peer-reviewed publications in scholarly journals – submitted	
Books	
Book chapters	
Reports and monographs (including policy briefs and best practices reports)	
Conference presentations and posters presented	
Web-based products (Blogs, podcasts, Web-based video clips, wikis, RSS feeds, news aggregators, social networking sites)	
Electronic products (CD-ROMs, DVDs, audio or videotapes)	
Press communications (TV/Radio interviews, newspaper interviews, public service announcements, and editorial articles)	
Newsletters (electronic or print)	
Pamphlets, brochures, or fact sheets	
Academic course development	
Distance learning modules	
Doctoral dissertations/Master's theses	
Other	

Part 2

Instructions: For each product, publication and submission listed in Part 1, complete all elements marked with an "*."

Data collection form: Peer-reviewed publications in scholarly journals – published	
*Title:	
*Author(s):	
*Publication:	
*Volume: *Number: *Year: *Page(s):	
*Target Audience: Consumers/Families Professionals Policymakers Students	
*To obtain copies (URL):	
Key Words (No more than 5):	
Notes:	
Data collection form: Peer-reviewed publications in scholarly journals – submitted	
*Title:	
*Author(s):	
*Publication:	
*Year Submitted:	
*Target Audience: Consumers/Families Professionals Policymakers Students	
Key Words (No more than 5):	
Notes:	
Data collection form: Books	
*Title:	
*Author(s):	
*Publisher:	
*Year Published:	
*Target Audience: Consumers/Families Professionals Policymakers Students	
Key Words (No more than 5):	
Notes:	

Data conection form for: Book enapters				
Note: If multiple chapters are developed for the same book, list them separately.				
*Chapter Title:				
*Chapter Author(s):				
*Book Title:				
*Book Author(s):				
*Publisher:				
*Year Published:				
*Target Audience: Consumers/Families Professionals Policymakers Students				
Key Words (no more than 5):				
Notes:				
Data collection form: Reports and monographs				
*Title:				
*Author(s)/Organization(s):				
*Year Published:				
*Target Audience: Consumers/Families Professionals Policymakers Students				
*To obtain copies (URL or email):				
Key Words (no more than 5):				
Notes:				
Data collection form: Conference presentations and posters presented				
(This section is not required for MCHB Training grantees.)				
*Title:				
*Author(s)/Organization(s):				
*Meeting/Conference Name:				
*Year Presented:				
*Type: Presentation Poster				
*Target Audience: Consumers/Families Professionals Policymakers Students				
*To obtain copies (URL or email):				
Key Words (no more than 5):				
Notes:				

Data coll	lection form: Web-based prod	ucts		
*Product:				
*Year:				
*Type:	blogs	podcasts	Web-based video clips	
	wikis	RSS feeds	news aggregators	
	social networking sites	Other (Specify)		
*Target Au	udience: Consumers/Families	_ Professionals Policymakers	Students	
*To obtain	copies (URL):			
Key Word	s (no more than 5):			
Notes:				
Data coll	lection form: Electronic Produ	ıcts		
*Author(s))/Organization(s):			
*Year:				
*Type:	CD-ROMs	DVDs	audio tapes	
	videotapes	Other (Specify)		
*Target Au	udience: Consumers/Families	_ Professionals Policymakers	Students	
*To obtain	copies (URL or email):			
Key Word	s (no more than 5):			
Notes:				
Data coll	lection form: Press Communic	cations		
*Author(s))/Organization(s):			
*Year:				
*Type:	☐ TV interview	Radio interview	☐ Newspaper interview	
	Public service announcement	☐ Editorial article	Other (Specify)	
*Target Au	udience: Consumers/Families	_ Professionals Policymakers	Students	
*To obtain	copies (URL or email):			
Key Word	s (no more than 5):			
Notes:				

	ion form: Newsletters		
*Year:		☐ Print	□ D oth
*Type:	_	_	∐ Both
•		Professionals Policymakers _	
		monthly quarterly annually	
Key Words (n	no more than 5):		
Notes:			
Data collect	ion form: Pamphlets, broo	chures or fact sheets	
*Title:			
*Author(s)/Or	rganization(s):		
*Year:			
*Type:	Pamphlet	Brochure	☐ Fact Sheet
*Target Audie	ence: Consumers/Families _	Professionals Policymakers _	Students
*To obtain co	pies (URL or email):		
Key Words (n	no more than 5):		
Notes:			
Data collect	ion form: Academic cours	e development	
*Title:		·	
*Author(s)/Or	rganization(s):		
*Year:			
*Target Audie	ence: Consumers/Families _	Professionals Policymakers _	Students
*To obtain co	pies (URL or email):		
Key Words (n	no more than 5):		
Dote celled	ion forms. Distance les —	ag madulag	
	ion form: Distance learnin	ng modules	
	6		

*Year:	_		
*Media Type:	blogs	podcasts	☐ Web-based video clips
	wikis	RSS feeds	news aggregators
	social networking sites	CD-ROMs	DVDs
	audio tapes	videotapes	Other (Specify)
*Target Audience	e: Consumers/Families Profe	essionals Policymakers	Students
*To obtain copies	s (URL or email):		
Key Words (no m	nore than 5):		
Notes:			
Data collection	form: Doctoral dissertations/N	Master's theses	
*Author:			
*Year Completed	l:		
*Type:	☐ Doctoral dissertation	☐ Master'	s thesis
*Target Audience	e: Consumers/Families Profe	essionals Policymakers	Students
*To obtain copies	s (URL or email):		
Key Words (no m	nore than 5):		
Notes:			
Other			
(Note, up to 3 ma	•		
	nization(s):		
*Year:	_		
*Describe produc	et, publication or submission:		
*Target Audience	e: Consumers/Families Profe	essionals Policymakers	Students
*To obtain copies	s (URL or email):		
Key Words (no m	nore than 5):		
Notes:			

Appendix B: Maternal and Child Health Bureau (MCHB) Strategic Research Issues

Strategic Research Issue #I. Public health service systems and infrastructures at the community, State and/or national levels, as they apply to different maternal and child health (MCH) populations ⁽¹⁾ based on demographic*, epidemiological, and/or other factors**.

(Correlates to MCHB Strategic Plan: FYs 2003-2007, Goal 4: Improve the Health Infrastructure and Systems of Care.)

*Demographic factors may include age and developmental status, gender, race/ethnicity, geography, economic status, etc.

** Other factors may include legislation, policies, etc that may influence availability and access to specific services.

IMPORTANT: To assist the reader in better understanding what is meant by MCHB Strategic Research Issue #I, the following are examples of possible areas of study addressing this issue. **They are only examples for illustrative purposes and do not constitute preferences for funding consideration**. The Bureau encourages translational research studies that specifically address issues related to MCHB investments and programs.

- Effectiveness of Screening Programs for Women: Study the individual, system, and community factors associated with screening and assessment programs that lead to referral and utilization of intervention for risk factors such as substance abuse and other conditions (e.g., obesity, diabetes) that may affect health outcomes for women and/or their children.
- Integrated systems of care specifically identified in Title V legislation for Children with Special Health Care Needs (CSHCN) (2): Determine the impact of Care Coordination (3) provided in the medical home and other settings on child and family outcomes for CSHCN.
- Study public-private partnership models for provision of services, such as public health provision of "wrap around" or "enabling" services, and their overall relative efficacy and compared with private practice or public clinic only.
- Investigate the processes involved in the **transition of adolescents** with special health care needs to adult health care, particularly the role of State health systems in facilitating or hindering transitions.

- Investigate the effects of the organization and delivery of comprehensive, continuous services on the health status and services utilization of children/adolescents, including those with special health care needs and those vulnerable for poor psychosocial outcomes (e.g., children/youth in foster care, involved with the juvenile justice system, or who are homeless).
- Assess the impact of integration of newborn screening program (NBS) on other MCH programs and enhanced data sharing at the State level and evaluate if screened children have access to medical homes (4).
- Assess emerging research in the prevention of dental caries in pregnant women and its effects on their children through the use of oral rinse and varnish, chlorhexidine, xylitol, and/or iodine.

Strategic Research Issue #II. MCH services and systems of care efforts to eliminate health disparities and barriers to health care access for MCH populations. These health disparities and barriers to health care access may include racial/ethnic, cultural, linguistic, gender, developmental, geographic, immigrant, underserved, economic considerations, etc.

(Correlates to MCHB Strategic Plan: FYs 2003-2007, Goal 3: Eliminate Health Barriers and Disparities.)

IMPORTANT: To assist the reader in better understanding what is meant by MCHB Strategic Research Issue #II, the following are examples of possible areas of study addressing this issue. **They are only examples for illustrative purposes and do not constitute preferences for funding consideration.** The Bureau encourages translational research studies that specifically address issues related to MCHB investments and programs.

- Determine the effectiveness, impact, and cost benefits of **cultural and linguistic competence** ⁽⁵⁾ in public health care and service systems.
- Study the causes for disparities in access to and utilization of early and adequate prenatal care in different regions of the country, differentiating by rural, urban and frontier areas, and the effects of such disparities.
- Investigate the effects of interdisciplinary and collaborative practice of health professions (including but not limited to nursing, oral health, pharmacy, mental health and pediatrics) on reducing barriers to health care access.
- Assess the impact of community-based genetic counseling and education programs in medically underserved communities to evaluate whether increased genetic counseling

and education programs will make a difference in access by underserved communities to genetic resources and services.

- Study interventions to reduce racial/ethnic disparities in pre-term/low birth weight and other infant health outcomes.
- Study the contribution of contextual effects on disparities in MCH outcomes.

Strategic Research Issue #III. Services and systems to assure quality of care $^{(6)}$ for MCH populations.

(Correlates to MCHB Strategic Plan: FYs 2003-2007,

Goal 5: Assure Quality of Care.)

IMPORTANT: To assist the reader in better understanding what is meant by MCHB Strategic Research Issue #III, the following are examples of possible areas of study addressing this issue. **They are only examples for illustrative purposes and do not constitute preferences for funding consideration**. The Bureau encourages translational research studies that specifically address issues related to MCHB investments and programs.

- Explore mechanisms of information transfer of evidence-based MCH strategies that lead to enhanced quality of provider practices and consumer behavior.
- Determine the effectiveness and impact of the current system of care (both public and private) to assure that women and infants receive risk-appropriate perinatal care.
- Study the extent to which children and adolescents needing emergency medical services actually receive them and the quality of care received from hospital emergency departments.
- Study the impact of specific characteristics of the medical home, such as the use of written "care plans," (7) on improvements in the quality of care for CSHCN.
- Study how duration, organization and content of visits for clinical preventive services affect the quality of anticipatory guidance/health counseling provided to children, adolescents and women.
- Investigate the factors that promote quality of health care service delivery, with attention to understanding the effectiveness and impact of interdisciplinary training of MCH professionals.
- Investigate factors that decrease fragmentation of MCH service delivery.

Strategic Research Issue #IV. Promoting the healthy development of MCH populations.

(Correlates with MCHB Strategic Plan: FYs 2003-2007,

Goal 2: Promote an Environment that Supports Maternal and Child Health.)

IMPORTANT: To assist the reader in better understanding what is meant by MCHB Strategic Research Issue #IV, the following are examples of possible areas of study addressing this issue. **They are only examples for illustrative purposes and do not constitute preferences for funding consideration**. The Bureau encourages translational research studies that specifically address issues related to MCHB investments and programs.

- Study the effectiveness of health promotion and prevention strategies for infant, child, adolescent and adult populations (e.g., **Bright Futures Guidelines**) that use coordinated strategies and a variety of venues involving the clinical setting, the community and the home environment.
- Conduct **longitudinal studies of health and normative development** in special populations of children such as minority children; children with special health needs; and children of low socioeconomic status (SES), rural, migrant and homeless backgrounds.
- Study the effectiveness of health promotion and prevention strategies to promote healthy weight and prevent **obesity** in children and adolescence.
- Study child, parental (including fathers) and family strengths, i.e., coping and resilience associated with pregnancy, childbearing and parenting; significant injuries; chronic and catastrophic disease conditions; and natural and man-made catastrophic events.
- Study the effects of family/professional partnerships and integrated community systems on the health (including mental and oral health) and development of children.
- Study the factors associated with health care utilization that positively influence health care utilization and preventive health behaviors of women at various stages of and throughout their life span.
- Study the effectiveness of community outreach workers in increasing **breastfeeding** duration rates in underserved populations.

DEFINITIONS

- ¹. **MCH Population** includes all of the Nation's women, infants, children, adolescents, and their families, including fathers and children with special health care needs (**MCHB Strategic Plan: FYs 2003-2007**)
- ². **Children with Special Health Care Needs (CSHCN)** those who have, or are at increased risk for, a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally (The American Academy of Pediatrics)
- ³. **Care Coordination Services** those services that promote the effective and efficient organization and utilization of resources to assure access to necessary comprehensive services for children with special health care needs and their families (**Title V sec. 501 (b) (3)**)
- ⁴. **Medical Home** a medical home can be a physician's office, a hospital outpatient clinic, a community health center or school-based clinic, as long as it provides the services that constitute comprehensive care continuous access to medical care; referral to pediatric medical subspecialties and surgical specialists; and interaction with child care, early childhood education programs and schools to ensure that the special needs of the child and family are addressed (**The American Academy of Pediatrics**)
- ⁵. **Cultural Competence** a set of behaviors, attitudes, policies, practices and structures that come together in a system, agency or among professionals and enable that system and agency or those professionals to work effectively in cross-cultural situations (**National Center for Cultural Competence, 2002**)

Linguistic Competence – the capacity of an organization and its personnel to communicate effectively with persons of limited English proficiency, those with low literacy skills or who are not literate, and individuals with disabilities (National Center for Cultural Competence, 2002)

- ⁶. **Quality of Care** 1) safe-avoiding injuries to patients from the care that is intended to help them; 2) effective-providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit; 3) patient-centered—providing care that is respectful of and responsive to individual preferences, needs and values and ensuring that patient values guide all clinical decisions; 4) timely-reducing waits and sometimes harmful delays for both those who receive and those who give care; 5) efficient-avoiding waste, including waste of equipment, supplies, ideas and energy; and 6) equitable-providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status (**National Committee for Quality Assurance-NCQA**)
- ⁷. **Care Plan** a comprehensive care plan combines a medical summary, an emergency care plan, and an action care plan. It provides information that can be shared across providers; a ready reference in an emergency; and an action plan that prioritizes concerns, identifies specific tasks to address concerns, assigns responsibility for tasks, evaluates outcomes, and is done in

collaboration with the child/youth and family	(Division of Services for Children with Special
Health Needs, MCHB, HRSA	

Appendix C: Key Terms for Project Abstracts

Access to Health Care Acculturation ADD/ADHD Asthma Autism

Breastfeeding

Capacity & Personnel
Cesarean
Child Care
Chronic Illness
Clinical Practice
Cognitive & Linguistic Development
Coordination of Services
Cost Effectiveness
Cultural Competence

Depression Developmental Disabilities Down Syndrome

Early Childhood Education Early Intervention Emergency Care

Fathers

Health Care Costs
Health Care Utilization
Health Disparities
Health Education & Family Support
Home Visiting
Hospitalization

Immigrant Populations Immunization Infections & Illness

Labor & Delivery Low Birthweight

Medicaid, SCHIP, & Health Insurance Medical Home Mental Health & Wellbeing Mortality Neighborhood Nutrition & Diet

Obesity & Weight Gain Oral Health

Parent-Child Relationship

Parenting

Perinatal

Physical Activity

Physical Growth

Postpartum

Pregnancy

Preconception Health

Preterm

Primary Care

Rural

Risk Behaviors

Safety

School Health Programs

School Outcomes & Services

Screening

Sexually Transmitted Diseases

SIDS

Sleep

Smoking

Social & Emotional Development

Special Health Care Needs

Stress

Substance Use

Telehealth & Health Information Technology

Trauma & Injury

Violence & Abuse

Well-Child Pediatric Care