"Fetal-Infant Mortality Review: Human Immunodeficiency Virus Prevention Methodology (FHPM)"

Supporting Statement A

Contact Information

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Supporting Statement

Section
A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests approval for a new data collection system called “Fetal-Infant Mortality Review:Human Immunodeficiency Virus Prevention Methodology” (FHPM) for 3 years.

Background

Remarkable progress has been made in preventing perinatal HIV transmission in recent years, following the introduction of antiretroviral therapy for the prevention of mother-to-child transmission in 1994. The number of infants perinatally infected with HIV has decreased dramatically: from 1,650 cases in 1991 to approximately 240-247 cases in 2005.

Despite advances in interventions to prevent perinatal HIV transmission, including antiretroviral drugs, elective cesarean delivery, and avoidance of breastfeeding, between 100 and 200 infants are perinatally infected with HIV in the United States each year. Many of these cases result from missed prevention opportunities, such as lack of prenatal HIV testing, prenatal care, or antiretroviral prophylaxis.

Currently CDC recommends that opt-out HIV testing should be included in the routine panel of screening tests performed in health-care settings for all pregnant women, and that pregnant women in high-prevalence areas be retested during their third trimester. While a number of states and territories have adopted these recommendations since their publication in 2006, many of the annual cases of perinatal HIV are the result of women who were not tested for HIV early enough in their pregnancies, or who were never tested at all. Since almost a quarter of the estimated 120,000 – 160,000 women of childbearing age in the United States who are infected with HIV do not know their status, prenatal HIV testing and prenatal care remain crucial opportunities for providing preventive interventions.

Every case of perinatal HIV can be viewed as a sentinel event, often resulting from a missed opportunity to prevent mother to child HIV transmission. The Fetal Infant Mortality Review-Human Immunodeficiency Virus Prevention Methodology (FHPM) is designed to identify and address missed prevention opportunities at the

community level. FHPM will be a CDC National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Prevention (NCHHSTP) funded extramural project at 10 sites, and will be conducted in partnership with the National Fetal and Infant Mortality Review Program, CityMatCH, and participating communities.

CityMatCH is a "freestanding national membership organization of city and county health departments' maternal and child health (MCH) programs and leaders representing urban communities in the United States."

Participating community sites will be selected through a competitive application process. Funds will be administered through CityMatCH, which will also maintain the National FHPM Resource Center to provide training, technical assistance, and capacity building for selected sites.

CDC also plans to launch the Fetal-Infant Mortality Review-Human Immunodeficiency Virus Data System (FHDS) in 2011, a secure, web-based data storage system that will be utilized by participating sites.

The original Fetal-Infant Mortality Review (FIMR) methodology was an approach designed to lead to community-level improvements in maternal and infant health outcomes. The methodology consists of four steps: Data gathering, case review, community action, and changes in community systems.

FHPM has adapted these steps in order to evaluate and address the causes of perinatal HIV transmission. This will be the first program to approach perinatal HIV prevention using a community-based systems investigation and improvement strategy.

This proposed information collection is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) to "… cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies related to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man…". (**Attachment 1**)

Privacy Impact Assessment

CDC NCHHSTP, in partnership with CityMatCH, will manage and direct the project. Participants' data will be de-identified before use. De-identified data will be stored electronically at participating sites in a secure, password-protected computerized database. All hardcopies will be stored securely in a locked file cabinet at each project office, and will be destroyed after review. CDC will not have access to any personal identifiable information that may be collected for the project.

As mentioned above, CDC plans to launch a web-based data system in 2011, which will provide a centralized, secure system that may be accessed and utilized by FHPM sites. All data in FHDS will be password protected and de-identified.

Overview of the data collection system

During FHPM's first stage, each of the selected FHPM sites will identify cases of perinatal HIV based on a pre-established case definition, and the cases will be prioritized for community review.

The "Maternal Interview Form" (**Attachment 3a**) will be administered to participating mothers by a trained interviewer in the participant's home, or another location agreed upon by the mother. Eligible women will be contacted by site staff as soon as possible after giving birth to determine their interest in participating. Signed consent will be obtained by a staff member before the interview (**Attachment 3a**). A maternal interview will only be conducted if signed consent is provided by the woman. Data collection can proceed using hospital records if there is no consent for an interview.

The maternal interview may be conducted in one of four languages: English, Spanish, French, or Creole, depending on the language preferences of the mother. There will be no cost to participants beyond their time, and women will complete a "Maternal Informed Consent Form" (**Attachment 4a**), which explains that they may decline to be interviewed, refuse to answer any questions, and may terminate the interview at any time.

The only interaction with patients will occur during the consent process and maternal interview. Each of the ten FHPM sites will conduct approximately 30 maternal interviews annually, for an overall total of 300 interviews each year. Face-to-face interviews will average 1.5 hours in duration and will not need

to be repeated, unless a woman has a second pregnancy and is selected for case review under the priority assessment, and consents to participate a second time. When the FIMR-HIV Data System (FHDS) is implemented, each of the ten sites will be asked to send its data to the FHDS.

In addition to the maternal interview, data for selected cases will be collected from a variety of other sources, including medical, public health, and case management records. FHPM will train and employ its own data abstractors for this purpose, so the data collection process will not burden clinics or hospitals.

After the data collection phase, a multidisciplinary case review team (CRT) will conduct a regularly scheduled case review session. CRTs will see only de-identified data during their case review sessions, and will review at least three cases per session in order to better identify trends. The team will discuss the community-level systems failures which may have led to the cases of perinatal HIV transmission in question, and will draft a summary statement. During the session the CRT will also work to identify strengths and weaknesses in the community's system to provide care and interventions to prevent mother-to-child HIV transmission. The CRT will be comprised of a broad variety of health care professionals, institutions, agencies, and other maternal and child service organizations within the community.

The recommendations and findings of the CRT will then be passed on to a Community Action Team (CAT), which will be a diverse, broad-based group of community leaders and representatives capable of defining and initiating changes in the local systems. After reviewing the CRT's summary, the CAT will draft a summary and action plan. The action plan will be based on the findings of the CRT, and will address a multitude of social, cultural, economic, educational, and health issues within the community.

The investigators at participating sites will maintain electronic, de-identified data indefinitely (see section A-10). After the implementation of the FHDS, CDC will also manage de-identified data via the web-based system.

Items of Information to be collected

Participating sites will collect name, date of birth, race, ethnicity and other demographic data for participating women. Data on HIV testing, timing of HIV diagnosis, prenatal care, and contact with other healthcare providers, experiences during labor and delivery, HIV care beliefs, substance use/abuse, social support, family planning, language barriers, and other qualitative data will also be collected during the maternal interview (**Attachment 3a**).

FHPM staff will also collect data on women and infants' receipt of care as documented in relevant health records. Data will be extracted from physician and hospital records, and birth certificates. This data collection will not place any burden on health facilities or healthcare providers.

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age.

There will be no websites or internet content directed at children under the age of 13.

2. Purpose of Use of the Information Collection

NCHHSTP is considering ways to accomplish its goal of eliminating perinatal HIV transmission in the United States, and has incorporated FIMR-HIV into a framework to do so.

FHPM has adapted the continuous cycle of improvement approach used by the Fetal and Infant Mortality Review (FIMR) in order to address barriers to PMCT interventions at the community level, and to identify and execute community level changes for improved perinatal prevention efforts. This is the first program that combines community-based systems investigations and improvements in an effort to prevent mother-to-child HIV transmission.

Data collected by FHPM will primarily serve to inform and improve local health systems in order to prevent future perinatal HIV transmissions. This data will provide a clearer picture of the systems-level strengths and weaknesses in participating communities. As such, FHPM's findings will be limited in their generalizability. Data for FHPM will be collected from a small number of sites across the country, which will apply to be part of the project and therefore will not be randomly selected. Cases reviewed at each site will be prioritized in order to best

identify systems failures, and will not be randomly selected. The results from FHPM are intended to provide an in-depth look at local health systems within each participating community, and should not be generalized to the experiences of all HIV-infected pregnant women or their communities. The lessons learned from this project will, however inform CDC's efforts at eliminating perinatal HIV transmission in the United States.

The results of this information collection will be analyzed and used for local and national public health planning, reported in scientific publications in peer-reviewed scientific and public-health journals, and presented in abstract form at scientific and public-health meetings.

Privacy Impact Assessment Information

Individually identifiable information (IIF) will be collected during the maternal interview (**Attachment 3a**) and the chart abstraction. Completed paper copies of the data collection forms will be stored in a secured, locked location. Data will be de-identified before entry into the electronic, password-protected database, and hard copies will be destroyed after each case review session.

All information used in the case review will be de-identified, including removal of patient, provider, and hospital/clinic names. Because private information will be collected a loss of privacy could potentially result in harm to the participant during the short period of time before IIF is destroyed.

No IIF will be available to or shared with the CDC. Any data maintained by the FHDS will be de-identified before entry, and identifiable data will be stored securely at site locations until case review, after which they will be destroyed.

3. Use of Improved Information Technology and Burden Reduction

De-identified data will be entered into a computer-based, password-protected software system. In the future all data will be stored on the FIMR-HIV Data System (FHDS), which is currently in development. FHDS will be password protected and will be accessed via the internet by approved users from participating organizations. Electronic copies of the data will be de-identified during data entry, and the paper copies will be destroyed after case review.

4. Efforts to Identify Duplication and Use of Similar Information

FHPM is the first adaptation of the FIMR methodology to the prevention of perinatal HIV. A search of PubMed for community level perinatal HIV prevention projects did not reveal any similar projects in published articles or abstracts. An internet search located several community-level perinatal HIV case review programs, none of which utilized the National FIMR methodology, maternal interviews, or CRT and CAT teams.

FHPM is unique in its utilization of the FIMR methodology. Because maternal interviews are not a part of HIV surveillance or prevention programs, the data collected provide rich, in-depth information on women's experiences with the local health and social-service systems. These data are not collected by other programs or intervention efforts due to a variety of limiting factors. These include high costs, time constraints, and the IRB process. This information gathering will complement perinatal prevention efforts in communities, while revealing community-level systems issues not otherwise identified.

5. Impact on Small Business or Other Small Entities

The collection of information will not impact independently owned small businesses. FHPM will train and employs its own data abstractors, so participating clinics and hospitals will not be burdened by the data collection process.

Data abstractors will be hired to conduct the medical record abstractions, not staff of hospitals or other healthcare facilities. Similarly maternal interviewers will be hired to contact and conduct the interviews. As a result there will be no burden on small entities.

Individuals who are a part of the CRT and CAT will be invited to participate, and may decline if the time commitment is too demanding. Individually-identifiable data will not be collected or maintained from any member of the CRT or CAT.

6. Consequences of Collecting the Information less Frequently

Participating women will complete a single 1.5 hour interview, unless a woman has a second pregnancy and is selected for case review under the priority assessment, and consents to participate a second time. Chart abstractions will also be performed one time for each case by trained abstractors employed by FHPM.

There are no legal obstacles to reduce the burden.

7. Special Circumstances relating to the Guidelines of 5 CFR 1320.5

The request fully complies with the guidelines of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60 day notice to solicit public comments was published in the Federal Register on 1/10/2011 (Volume 76, Number 6, Pages 1433-1434) (**Attachment 2**). There were no comments received in response to the 60-day federal register notice.

This protocol was developed collaboratively between the National Fetal and Infant Mortality Review Program (NFIMR), CityMatCH, and the Centers for Disease Control and Prevention. The persons consulted outside of the CDC are:

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9. Explanation of Any Payment or Gift to Respondents

Each FHPM site will be responsible for providing a small token of appreciation consisting of a $50.00 gift card for women who agree to participate in the maternal interview.

Hospitals, clinics, or other agencies that allow chart abstractions of their patient files will not be provided any tokens of appreciation for their participation.

10. Assurance of Confidentiality Provided to Respondents

Privacy Impact Assessment Information

This information collection is not subject to the Privacy Act.

Data will be collected by FHPM partner staff at participating sites. The data will be stored in a locked file cabinet in a secure location. Staff will collect date of birth, gender, race, and ethnicity of participants but this information will be de-identified before it is transmitted to or accessed by CDC. Identifiable information will not be filed or retrieved by the name of the individual by CDC or FHPM. Identifiable data will be destroyed after the CRT review session.

The data collected will be stored in a password-protected computerized database. A secure, web-based data system is currently under development. Each participant will be assigned a unique identifying number which is the only identification visible in the database. The participant identification number in the FHPM database will be unlinked from personal identifiers after the Case Review Sessions. The FHPM number will be used for each record in the database; no contact or personal information will be linked to the records.

Participants' names and contact information will be kept in a separate locked file cabinet at local site offices. All identifiable data will be destroyed after the CRT review session. CDC employees will not have access to identifiable data at any time.

The Human Subjects Tracking Form for the Cooperative Agreement number TS-1447(ATPR CoAg) titled "Eliminating Perinatal HIV:

Continuous Quality Improvement", has been approved by CDC. This granted FHPM Non-Research status (**Attachment 5a:** Project Determination as Non-Research – Centers for Disease Control and Prevention).

Participating mothers will be interviewed by an FHPM staff member. Interviews will be conducted in the participant's home, or another location of the mother's choosing. The interview will be administered in a private or semi-private setting that is chosen by the participant. The interviewer will record data on the "Maternal Interview Form" (**Attachment 3a:** FIMR/HIV Maternal Interview Form).

Measures will be taken to ensure the security of participants' data once the interview and chart abstraction has been completed. After each interview or abstraction project staff will enter de-identified information in a secure computer-based data system available to all project sites. The software ensures that entered data is password protected and can only be modified or viewed by designated data managers with the password and access to the software. All files will be date and time stamped for verification of the file being received and password protected. The new data system currently being developed will be similar, save that the data will be entered, stored, and accessed via a web-based system. Appropriate measures of security including passwords and encryption will be utilized to ensure the utmost security. Any data entered electronically will be de-identified, including the removal of patient and clinic names. Paper copies will be stored in a secure, locked location and will be destroyed after review.

The consent form clearly indicates that participants voluntarily agree to be interviewed, and there are no mandatory requirements that they participate. Participants will also be free to terminate the interview at any time. All data will be handled in a secure manner by the project team.

11. Justification for Sensitive Questions

FHPM will ask pregnant or recently post-partum HIV-infected participants questions of a sensitive nature. By nature of the project, FHPM will include only women who are HIV-infected and currently or recently pregnant. Asking them to describe their experiences before, during, and after their recent pregnancy will provide FHPM with important information about community-level systems of care for HIV-infected pregnant women and HIV-exposed

infants. The results may allow CDC to design and target interventions in the future to better address the needs of HIV-infected pregnant women in participating communities in order to prevent future cases of perinatal HIV transmission.

Questions pertaining to sexual behavior, physical abuse, and drug use will be asked of the participants. These questions will be needed to evaluate HIV transmission risk, experiences during pregnancy, unmet healthcare needs, and gaps within the community level systems. Interviewers will be trained to provide participants with appropriate local referrals for ongoing healthcare needs at the time of the interview.

Past history of HIV testing will be requested to determine when/if the participant had been tested for HIV in the past and when/if she was tested or retested during her latest pregnancy. Because only HIV-infected pregnant or recently pregnant women will be included in FHPM, this information will be vital to the project. This information may affect healthcare insurance or employability. It will be essential to know when the participant was last tested, and when the participant was first diagnosed with HIV in order to determine missed opportunities for perinatal HIV prevention.

Questions pertaining to past history of discrimination and experiences with healthcare professionals will be asked of the participants. These questions will be needed to evaluate social constraints the participant has experienced in her lifetime and the areas in which the community healthcare system may need to improve. Such social constraints and perceptions of the healthcare system may adversely affect attitudes towards prenatal care, HIV treatment during pregnancy, family planning, etc. This information will be used to identify weaknesses in community-level systems, and to make improvements that will prevent future cases of mother-to-child HIV transmission.

12. Estimates of Annualized Burden Hours and Costs

A. This information collection will occur over 3 years. Data collection will occur at ten participating sites around the United States. Each site will review approximately 30 cases each year. Reviewed cases will consist of a maternal and infant chart review, abstraction of records from other health and social service agencies, and one maternal interview.

Cases for inclusion in FHPM are defined as “HIV-exposed infant/fetus ≥ 24 weeks gestation and < 24 months of age at the

time of the review." Cases for review will not be randomly selected at each site, but rather will be prioritized for review based on key indicators such as an HIV-infected infant or lack of antiretroviral prophylaxis in labor and delivery.

Public health personnel or clinicians involved in each woman's care will first ask each woman for permission to be contacted by FHPM staff. With this permission, FHPM staff contact each woman and describes the project by reading the informed consent. Once a woman agrees to participate and signs the informed consent form (**Attachment 4**), she will be interviewed in her home. Maternal interviews will last approximately 1.5 hours, and will only occur once, unless a woman has a second pregnancy and is re-selected for review. There will be no cost to participants beyond their time.

Table 12.A Estimate of Annualized Burden Table

Estimated Annualized Burden Hours for Years Through 2011

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Response (in hours)	Total Burden (in hours)
HIV-Infected Pregnant or recently post-partum women	FIMR-HIV Maternal Interview Form	300	1	1.5	450

Table 12.B Estimated Annualized Burden Costs

Type of Respondent (Form Name)	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
FIMR/HIV Maternal Interview Form	450	$20.23	$9,103.50

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There will be no costs to respondents other than their time.

14. Annualized Cost to the Federal Government

The project will be an extramural project funded by NCHHSTP and carried out by CityMatCH at the University of Nebraska Medical Center. The cost of the project for 3 years is estimated to be $869,892.

Exhibit A.14: Estimates of Annualized Costs to the Federal Government.

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Project Officer, Principal Investigator (GS-13 .2 FTE)	$21,800
	CDC Co-Principal Investigator, (GS-14, .1 FTE)	$16,800
	CDC Co-Investigator (GS-13, .15 FTE)	$16,350
Operational	Travel – two trips for Project Officer and two trips for Co-PI	$10,000
	Subtotal, Direct Costs to the Government	$64,950
Contractor and Other Expenses	Cooperative Agreement to CityMatCH (year 1, TBD ongoing) Maintain a National FIMR-HIV Resource Center to provide training, technical assistance and capacity building for sites.	$225,014
	Subtotal, Contracted (CoAg) Services	$225,014
	TOTAL COST TO THE GOVERNMENT	$289,964

Salary estimates were obtained from the United States Public Health Service Commissioned Corps Website (http://dcp.psc.gov/) and the OPM salary scale (http://www.opm.gov/).

The annualized cost to the Federal Government is $289,964.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Exhibit A.16: Project Time Schedule

Activity	Time Schedule
Announce funding for National Resource Center (NRC) expansion	1 months after OMB approval
Finish web-based data system development	1-2 months after OMB approval
Collect and enter data from existing sites	3-4 months after OMB approval
Analysis of full data set	4-5 months after OMB approval
Award NRC funds	4-5 months after OMB approval
Disseminate results	6-10 months after OMB approval
Provide training and technical assistance to sites	10-13 months after OMB approval
Collect and enter data from all sites	(Ongoing through 36 months) Beginning 14 months after OMB approval
Analysis of full data set	(Ongoing through 36 months) Beginning 15 months after OMB approval
Dissemination of results	(Ongoing through 36 months) Beginning 20 months after OMB approval
Periodic updates and annual reports to Health and Human Services	(Ongoing annually through 36 months) Beginning 20 months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exception is requested.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)

No exception is requested.