Supporting Statement A

for

Assessment of the Psychosocial Impact of Newborn Screening for Congenital Cytomegalovirus (CMV) Infection

New

Project Officer:
Stephanie Bialek
Team Lead
Herpesvirus Epidemiology Team
Epidemiology Branch
Division of Viral Diseases
National Center for Immunization and Respiratory Diseases
P. (404) 639-7785
E. Sbialek@cdc.gov

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The items contained within this Information Collection Request are new activities with a purposed one-year project period. The length of data collection requested for OMB-PRA approval is one year. The Centers for Disease Control and Prevention (CDC), National Center for Immunization and Respiratory Diseases (NCIRD) request approval for these activities as authorized by the Public Health Service Act, Title 42 United States Code—The Public Health and Welfare, Chapter 6A—Public Health Service, Subchapter II—General Powers and Duties, Part A—Research and Investigations (see *Public Health Service Act, 42 USC Sec. 241* Attachment 1).

Background

CDC promotes prevention of disease, disability, and death through immunization and by control of respiratory and related diseases. This research is funded jointly by NCIRD and the The National Center on Birth Defects and Developmental Disabilities (NCBDDD), which promotes the health of babies, children, and adults, with a focus on preventing birth defects and developmental disabilities and optimizing the health outcomes of those with disabilities.

Each year in the United States, more than 30,000 children are born with congenital cytomegalovirus (CMV) infection. Approximately 80% develop normally, while the remaining 20% are born with or subsequently develop disabilities such as hearing loss or mental retardation. A similar number of children are affected by serious CMV-related disabilities than by several better-known childhood conditions, including Down syndrome and spina bifida.

The birth prevalence of congenital CMV infection is several times higher than the combined birth prevalence of all metabolic or endocrine disorders in the core U.S. newborn screening panel. Because newborn CMV screening is rarely performed, and because a definitive diagnosis of congenital CMV requires access to urine, saliva, or blood collected soon after birth, most infected children are never diagnosed. Newborn CMV screening offers some clear potential benefits, but few studies have assessed the potential for harm (e.g., increased parental anxiety, “fragile child syndrome”).

The purpose of this information collection is to understand the psychosocial impact of newborn screening on parents whose infants underwent CMV screening as part of a routine infant CMV screening program in Houston, Texas. The potential study population includes approximately 70 CMV-infected children who were symptomatic at birth, 100 CMV-infected children who were asymptomatic at birth (20 of whom developed sequelae), and 50 controls that were CMV-uninfected. The goals of this information collection are to 1) Document the positive and negative psychosocial impacts of newborn CMV screening on parents and their children; 2) Identify modifiable factors that might increase positive psychosocial impacts and decrease negative psychosocial impacts of newborn CMV screening; 3) Use what is learned about psychosocial impacts to identify key messages that parents need relative to newborn CMV screening and follow-up; and 4) To learn what challenges are associated with obtaining a congenital CMV diagnosis in the absence of CMV newborn screening.

1.1 Privacy Impact Assessment

I. Overview of the Data Collection System

This data collection is intended for the parents of children who are subjects from previous CMV studies. The parents are stratified into four categories:

- Parent Group 1 (PG1) – Child screened positive for congenital CMV at birth, asymptomatic at birth, but did not develop sequelae
- Parent Group 2 (PG2) – Child screened positive for congenital CMV at birth, asymptomatic at birth, but did subsequently develop sequelae (e.g., hearing loss)
- Parent Group 3 (PG3) – Child was diagnosed with congenital CMV and had symptoms at birth
- Parent Group 4 (PG4) – Child screened negative for congenital CMV at birth

There are two main data collection systems for this project: qualitative (i.e., focus groups and interviews) and quantitative (i.e., survey). The qualitative data will be collected by Kirby Marketing Solutions (KMS), a contractor to Baylor College of Medicine (BCM). BCM will collect the quantitative data.

For the qualitative research KMS will conduct interviews or focus groups with PG1, PG2, and PG3. The interview/focus group data will be collected using digital audio recordings and handwritten notes. The digital audio recordings will be transcribed by an outside transcription service. The handwritten notes will be digitally captured and scanned by OCR recognition software and stored on KMS computers. The handwritten notes are used to capture and summarize key points that a verbatim transcription does not provide. All digital transcriptions will be entered into Nvivo, a text analysis software program, and analyses will include comparisons within and between parent groups.

The quantitative data collection will include all four parent groups. BCM will mail written surveys to prospective participants (see attachment 8). When surveys are returned, BCM staff will enter the data into a database. Data analyses will be carried out by BCM and the CDC. When the research project is complete and all reports have been accepted as final, both the qualitative data will be removed from any KMS computers and delivered to Baylor for archival storage.

The study protocol has been submitted to the IRB of BCM which has requested some minor revisions. Via verbal consent, participants will be informed that the focus groups and interviews they participate in will not release personal identifiers, are voluntary, and they will not be coerced into enrolling in this research protocol. Participant privacy will be protected by addressing individuals by first name only during interviews.

II. Items of Information to Be Collected

The respondent universe is estimated based on Baylor's information on previous CMV study participants. A subset of parents will be recruited for the qualitative research. Because the potential study population is small, the recruitment for the quantitative research will be conducted among all previous study participants who have email accounts on file with Baylor. This is currently estimated to be:

Table 1.1
Potential Recruits

Parent Category	Number of Parents for	Number of Parents for

	Qualitative	Quantitative
Parent Group 1 (PG1) – Child screened positive for congenital CMV at birth, asymptomatic at birth, but did not develop sequelae	36	105
Parent Group 2 (PG2) – Child screened positive for congenital CMV at birth, asymptomatic at birth, but did subsequently develop sequelae	20	20
Parent Group 3 (PG3) – Child screened positive for congenital CMV at birth, symptomatic at birth, and may or may have not subsequently developed sequelae.	15	55
Parent Group 4 (PG4) – Child screened negative for congenital CMV at birth.	0	50
Totals	71	230

This research is designed to help us better understand the positive and negative psychosocial impacts of learning a child's congenital-CMV status at birth and during the critical follow-up years (up to approximately age 5). The qualitative data instruments will be either focus group guides or interview guides (see attachments 3, 5, 6). Both cover similar topics for the parents. The topics we plan to ask parents about include typical psychosocial impacts, such as parent and family emotional, mental, marital, or financial stress and impacts on siblings due to family stress or extra attention to a child found positive for congenital-CMV (e.g., follow-up testing procedures). These questions are being developed based on a validated instrument, the Parent Stress Scale (PSS).We will also explore other domains of quality of life issues, such as those found in the Psychosocial Consequences Questionnaire (PCQ). The qualitative instruments are open-ended so we can explore additional topics that might not be documented in the PSS, PCQ, or the PSI (noted below), especially for parents managing health-threatening news for their young child.

The quantitative instrument is designed to help us learn if there are psychosocial differences between parents whose child is positive for congenital CMV versus those whose children are negative. These questions are being developed based on the well researched Parent Stress Index (PSI). The PSI has been used extensively in many studies of different pediatric patient groups . Furthermore, the Swedish version of the instrument (SPSQ) is also documented in scientific studies to be useful with parents whose children are in clinical treatment.

Thirty-six items are broken into three domains: Parental Distress (PD), Parent-Child Dysfunctional Interaction (P-CDI), and Difficult Child (DC), which combine to form a Total Stress index for parents. The questionnaire is short and easy for parents to answer. It is written at an 8th grade reading level. Empirical validity has been shown to exist in studies that focused on parenting of Head Start children, medication adherence, and cognitive development of infants.

Recruitment:
BCM has a long-term relationship with most parents of the children enrolled in previous CMV studies. The PI, Dr. Gail Demmler, will direct her staff to recruit parents to this qualitative and quantitative research project. Qualitative recruits will be a subset of parents whose children have particular characteristics (see Table 1.1). Quantitative data collection recruiting will attempt to obtain participation from a larger sample (approximately 230) of participants who have email accounts on file with BCM.

For the qualitative interviews and focus groups, a subset of previous study participants will be identified based on their child's CMV status and subsequent development of sequelae (see Table 1.1). BCM staff will first contact parents through a recruitment letter (see attachments 4 and 7). Follow up contact will be via phone, where each person will be verbally told about the

study (see attachment 10). If they are interested in participating and agree to be interviewed (individually or in a focus group), the time and location will be relayed via phone. If at any time they do not wish to participate, they will be told they can leave or disconnect from the encounter. They will also be advised that the questions will be about positive and negative impact of CMV screening on parents and families. They will also be advised that as a token of appreciation they will receive an incentive for travel, childcare, and their willingness to be in either an interview or focus group.

Recruitment for the quantitative data collection will be similar; BCM staff will conduct all of the recruitment. In this case the recruitment will be a letter asking parents to fill out an enclosed survey (see attachment 8). Participants will be provided with a self-addressed stamped envelope to return the survey.

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

No website content directed at children under 13 years of age is involved in this information collection.

A.2. Purpose and Use of Information Collection

The overall purpose of this research is to 1) Document the positive and negative psychosocial impacts of newborn CMV screening on parents and their children; 2) Identify modifiable factors that might increase positive psychosocial impacts and decrease negative psychosocial impacts of newborn CMV screening; 3) Use what is learned about psychosocial impacts to identify key messages that parents need relative to newborn CMV screening and follow-up; and 4) Learn what challenges are associated with obtaining a congenital CMV diagnosis in the absence of newborn CMV screening.

Much of the potential study population is unique in that it represents a group of people whose children experienced newborn CMV screening as part of a previous research study. Universal screening has not been recommended by medical associations or state or federal governments and as a result newborn CMV screening is not typically performed. The parents' experience with CMV screening and follow-up will help inform decisions about whether newborn CMV screening would be good public health policy. This study represents the first assessment of the experiences of parents whose children were screened for CMV at birth.

The qualitative and quantitative data collections will be analyzed and described in manuscripts intended for scientific peer-review and publication in scientific journals. The manuscripts will provide an assessment of the potential for harm and benefit associated with newborn CMV screening. This assessment can also be included in broader assessments of the utility of newborn CMV screening as public health policy that may be carried out by government advisory committees, medical associations, or other policy makers.

2.1. Privacy Impact Assessment

1. Research data, written and recorded, will be kept under lock and key within the laboratory of the Principal Investigator (PI) at Texas Children's Hospital Feigin

Center Suite 1150. Texas Children's Hospital is a BCM-affiliated institution. The only individuals who will have access to these data by key will be the PI and PI staff. Although KMS will temporarily have some research data, it will not include personal identifiers.

2. No research data with personal identifiers will leave Texas Children's Hospital once collected. Therefore, the proposed data collection will have little or no effect on the respondents' privacy. Participants will be informed that their participation in the information collection is completely voluntary.

A.3. Use of Improved Information Technology and Burden Reduction

This study will not employ automated, electronic, mechanical or other technological data collection techniques for the focus groups, interviews, or survey. Respondents' use of information technology is not applicable since all data will be collected through interpersonal interactions using pen-and-paper instruments.

A.4. Efforts to Identify Duplication and Use of Similar Information

No other federal agencies collect this type of information. Baylor College of Medicine and Kirby Marketing Solutions conducted a comprehensive scientific literature review of multidisciplinary fields. This project builds on the information found through the literature review, but the information currently available has significant gaps, is outdated, and does not adequately address the topics of interest. There is no other project that duplicates the proposed efforts.

A.5. Impact on Small Businesses or Other Small Entities

There is no burden on small businesses or small entities. No small businesses will be involved in this activity. The focus groups, interviews, and surveys will be completed at the convenience of the participants and will not impact the participants' employers.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection effort and respondents in each phase will be asked to respond only once. If the requested data collection was not conducted, CDC would be unable to gather valuable information that could lead to important public policy decisions regarding newborn CMV screening. Universal screening has not been recommended by medical associations or state or federal governments and as a result newborn CMV screening is not typically performed. The parents' experience with CMV screening and follow-up will help inform decisions about whether newborn CMV screening would be good public health policy. This study represents the first assessment of the experiences of parents whose children were screened for CMV at birth.

There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with regulation 5 CFR 1320.5.

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

A. A copy of the agency's 60-day Federal Register Notice is attached (*60-day Federal Register Notice* Attachment 2). The notice, as required by 5 CFR 1320.8 (d), was published on 9/20/2012 (Vol. 77, No. 183). No substantive public comments were received in response to this notice.

B. Consultations with Individuals Outside the Organization: CDC's NCIRD and NCBDDD have collaborated on this data collection effort with the BCM PI and her staff and with Susan Kirby of KMS.

Non-CDC collaborators:

Gail Demmler-Harrison, M.D.
Feigin Center Suite 1150
1102 Bates Street
Houston, TX 77030
gdemmler@bcm.edu
832-824-4330
Fax 832-825-4347

Alison Chantal Caviness, M.D., M.P.H., Ph.D.
6621 Fannin St., MC 1-1481
Houston, TX 77030-2399
ACCavine@texaschildrens.org
832-824-5497
Fax 832-825-5424

Holly Corwin, M.P.H.
Feigin Center Suite 1150
1102 Bates Street
Houston, TX 77030
hcorwin@bcm.edu
832-824-4330
Fax 832-825-4347

Susan Kirby, Dr.P.H.
Kirby Marketing Solutions
susan@kirbyms.com
858.245.2456
Fax 858.769.4481

CDC collaborators:

Stephanie Bialek, M.D.
National Center for Immunization and Respiratory Diseases
1600 Clifton Road, Mailstop A-34
Atlanta, GA 30333
sbialek@cdc.gov
(404) 639-7785

Tatiana Lanzieri, M.D.
National Center for Immunization and Respiratory Diseases
1600 Clifton Road, Mailstop A-34
Atlanta, GA 30333
tmlanzieri@cdc.gov
(404) 639-3031

Michael Cannon, Ph.D.
National Center on Birth Defects and Developmental Disabilities
1600 Clifton Road, Mailstop E-86
mcannon@cdc.gov
404-498-6722

Denise Levis, Ph.D.
National Center on Birth Defects and Developmental Disabilities
1600 Clifton Road, Mailstop E-86
igc1@cdc.gov
404-498-0237

A.9. Explanation of Any Payment or Gift to Respondents

Interviews and focus groups participants will receive a small incentive as a token of appreciation for traveling to the Baylor College of Medicine and for participating in these activities. These activities are anticipated to take 60-90 minutes of time. This incentive is planned at $25 per participant.

Focus group and interview facilities at Baylor will not offer childcare services due to liability concerns, so the incentive needs to be enough to help the participants cover outside childcare costs if needed. It is assumed that the $25 incentive the women receive for participating in the groups would go toward the cost for off-site childcare to make it possible for them to attend.

Survey participants will not receive any payment for their participation in the survey.

The Council of Professional Associations on Federal Statistics recently conducted expert panels on the topic of reimbursing participants for research participation (http://www.copafs.org/reports/providing_incentives_to_survey_respondents.aspx), specifically for OMB. Part of the discussion of this panel was that the goal of federal government research is to produce information for the public good. Most participants felt that the emphasis should not be on proving that there is an exceptional need for incentives but rather on demonstrating the substantial benefit of the incentive. This list included several conditions. The ones most relevant to the proposed research are:

- When there are unusual demands on the respondent (e.g., lengthy interviews).

- When sensitive questions are being asked.

- If there is any out-of-pocket cost to the respondent (e.g., transportation cost to the interview site, sitting costs).

- If the population is a control group in an important (and perhaps expensive) study where it is imperative to keep most respondents in the control group sample or the result of the whole study could be vitiated.

These are the main reasons we are proposing an incentive for these participants.

A.10. Assurance of Confidentiality to Respondents

This submission has been reviewed by the CDC's NCBDDD Privacy Officer who has determined that the Privacy Act does not apply. Participants will provide information based on their experiences with newborn CMV screening and follow up of their child. While first names of participants will be known, participants will not be asked for personal information about themselves that could allow them to be identified by CDC.

Participation in the study is voluntary. Participants will be informed that the focus groups, interviews, or surveys they participate in will not collect or release personal identifiers. All data will be treated in a secure manner and will not be disclosed. Only the Baylor PI will have access to participant contact information.

IRB Approval: A study protocol has been submitted to the BCM IRB for this data collection. No Certificate of Confidentiality will be issued for this study

10.1. Privacy Impact Assessment Information

1. All study participants will be informed that their participation is voluntary. Verbal informed consent will be obtained from all enrolled participants at the time of participation. Survey respondents will be asked for information about their experiences with newborn CMV screening of their child. While first names of participants will be known during this data collection, participants will not be asked for personal information about themselves. All survey data will reside in a secure database accessible by password only.

2. Informed consent is associated with this data collection.

3. Completed surveys will be kept in a locked filing cabinet maintained by the BCM PI. Data from the written surveys will be entered into a secure database at BCM. Survey raw data can only be accessed by study collaborators and a password is required. This project will not maintain any Information in Identifiable Form (IIF). The legal authority to collect and maintain this data is granted by Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of confidentiality for health research and related activities (42 U.S.C. 242 b, k, and m(d)).

4. No individually identifiable info is being collected.

A.11. Justification for Sensitive Questions

Some of the questions we plan to ask in interviews, focus groups, and the survey might be construed by some parents to be sensitive. These include questions about stress issues in their marriages, personal life, family, financial, and with schools or medical providers. Many of the parents in the previous CMV studies have been meeting and working with the BCM PI for over 20 years. The current PI and other medical providers have previously reported parents freely discussing similar stress-related issues. Although some of these questions are sensitive in nature, they have been commonly and successfully asked of parents similar to those who will be in the study, including parents with children who have significant health problems.

Some of the items are of a sensitive nature because the impact we are assessing is designed specifically to understand sensitive issues, such as parenting, family, and marital stress. These attitudinal measures are included because they will provide more accurate representations of parenting and family stressors related to knowledge of a child's CMV status at birth and during the critical follow-up period of up to five years. These responses will significantly supplement current understanding of how knowledge of CMV status impacts parents, families, and the affected children. Without this information it will be very difficult to answer important policy related questions about the psychosocial impact of adding CMV screening to newborn screening programs.

During interviews and focus groups parents will only be addressed by their first names and no identifying information will be collected during these interviews or focus groups. No identifying information will be collected as part of the mail survey. Participants will be instructed they can choose to not answer questions, leave the interview, focus group, or survey without any repercussions of any kind. Consent for interviews and focus groups will be acquired verbally during recruitment and reviewed again at the beginning of each interview and focus group. Informed consent for the survey will be provided in the recruitment letter (attachments 4, 7).

A.12. Estimates of Annualized Burden Hours and Costs

It is estimated that 71 parents will participate in either individual interviews or focus groups and that 230 will participate in the mail survey. The interviews are planned to take 60 minutes while the focus groups will be held for 90 minutes. The survey is estimated to take 10 minutes per respondent to complete and mail based on previous administrations reported in the literature. Reading and responding to the focus group and interview recruitment letters is estimated to take 5 minutes each.

Table A.12.A.
Estimates of Annualized Burden Hours

Parent Category	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Parent Group 1	Focus Group Guide	36	1	1.5	54
	Focus group recruitment letter	50	1	5/60	4
Parent Groups 2 and 3	Interviewer guide	35	1	1	35
	Interview recruitment letter	50	1	5/60	4
Parent Groups 1,2,3, and 4	Survey	230	1	10/60	38
Total Burden Hours					135

Table A.12.B Estimated Annualized Burden Costs

The hourly wage for respondents was estimated using the Bureau of Labor Statistics mean hourly wage for all occupations from its most recent report of May 2011. This average hourly wage is $21.74. The total estimated cost burden on all survey respondents is $2,760.98 (127hr x $21.74). The estimated cost per respondent who participates in a focus group is $32.61; the cost per respondent who participates in an interview is $21.74; and the cost per respondent who completes a survey is $3.62.

Table A.12.B.
Annualized Cost To Respondents

Respondents	Respondents' Activity	Total Burden Hours	Estimated Hourly Wage	Respondent Cost
Parent Group 1	Focus group participation	54	$21.74	$1,173.96
Parent Groups 2 and 3	Interview participation	35	$21.74	$760.90
Parent Groups 1,2,3, and 4	Survey participation	38	$21.74	$826.12
	Total	127		$2,760.98

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

There are no capital or maintenance costs to survey respondents associated with this survey.

A.14. Annualized Costs to the Federal Government

The average annualized cost to the Federal Government to collect this information is $14,191. The federal government personnel estimate is based on cost of the Project Officer, who is responsible for the management and oversight of the project (Table A.14) and 3 additional staff members who are also responsible for oversight.

These figures include the costs of time to manage and oversee the project and time spent consulting on all areas of project development.

Table A.14.

Federal Government Personnel Costs			Total
	CDC Project Officer (CC 0-6 at 2% time)	Management and oversight of project	$4141
	CDC collaborator (GS-14 at 5% time)	Consultation on all areas of project development	$6230
	CDC collaborator (GS-14 at 5% time)	Consultation on all areas of project development	$2050
	CDC collaborator (GS-13 at 2% time)	Consultation on all areas of project development	$1770
TOTAL			$14,191

A.15. Explanations for Program Changes or Adjustments

This is new data collection; therefore, program changes and adjustments do not apply.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Recruitment for study participants will begin within 2 weeks after OMB approval. The entire study will be completed within 4 months. Table A16 below outlines the project time schedule by activity.

Table A.16
Project Time Schedule

Activity	Time Schedule
Recruit interview and focus group participants	2 weeks after OMB approval
Conduct interviews and focus groups	6 weeks after OMB approval
Code and analyze data	8-12 weeks after OMB approval
Recruit participants for survey	14 weeks after OMB approval
Clean and analyze data. Produce reports.	16 weeks after OMB approval

Analysis Plan:

Data from the focus groups and interviews will be coded, compared, and analyzed using

Nvivo, a text analysis software. Salient topics and themes discussed across parents will be identified. Particular attention will be paid to positive and negative psychosocial impacts of parents from each parent category, one through three (see Table 1.1). The data from the mail survey is measured using both 4 point and 5 point Likert scales. There are thirty-six items in the Parent Stress Index-Short Form which are broken into three domains: Parental Distress (PD), Parent-Child Dysfunctional Interaction (P-CDI), and Difficult Child (DC), which combine to form a Total Stress scale. We will calculate overall scores and specific domain scores for each of the three parent domains. The overall and domain scores will then be statistically compared for the groups using the noted procedures which have been utilized in other similar studies .

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

The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

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