Supporting Statement A

for

Communications Research for the Development of Messages and Materials about Cytomegalovirus (CMV)

New

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted under the classification "new" request. The length of data collection requested for OMB-PRA approval is two years. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) is making this request 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

Cytomegalovirus (CMV) is the most common congenital infection in the U.S., causing disabilities in more than 5,500 children born each year.[1] Disabilities related to congenital CMV are more common than other well-known childhood conditions, such as Down syndrome, fetal alcohol syndrome, and neural tube defects,[234] and can include hearing or vision loss, mental retardation, psychomotor delays, and speech and language impairment.[5]

Congenital CMV infection is the result of intrauterine transmission of CMV infection from mother to fetus.[6] Specifically, congenital CMV infection occurs when a pregnant woman contracts a primary infection just before or during pregnancy. A fetus becomes infected when a mother comes into contact (through eyes, nose, or mouth) with saliva or urine from CMV positive children.[7] Congenital infection can also occur when a pregnant woman has a CMV reactivation or is re-infected with a different CMV strain. In addition, studies have indicated that sexual transmission is another important source of CMV infection, particularly for young urban women.[5] The incidence of CMV infection is also higher among racial and ethnic minorities and persons of lower socioeconomic status (SES).[683] Rates of congenital CMV infection are highest in urban, low-income, predominantly African-American populations in which the CMV prevalence rates among women of child-bearing age are high, suggesting that CMV exposures are occurring frequently in these populations.[5]

The Centers for Disease Control and Prevention (CDC) CMV prevention guidelines include (a) thoroughly washing hands with soap and warm water after activities such as diaper changes, feeding or bathing a child, wiping a child's runny nose or drool, handling a child's toys; (b) not sharing cups, plates, utensils, toothbrushes, or food; (c) not kissing on or near the mouth; (d) not sharing towels or washcloths; and (e) cleaning toys, countertops, and other surfaces that come into contact with a child's urine or saliva. Currently, awareness about congenital

[1] Centers for Disease Control and Prevention. (2010). Congenital CMV infection trends and statistics. Available at http://www.cdc.gov/cmv/trends-stats.html.

[2] Jeon, J., Victor, M., Adler, S.P., Arwady, A., Demmler, G., Fowler, K., Goldfarb, J., Keyserling, H., Massoudi, M., Richards, K., Staras, S. A. S., Cannon, M.J. (2006) Knowledge of congenital cytomegalovirus among women. Infectious Diseases in Obstetrics and Gynecology, Volume 2006, Article ID 80383, 1-7.

[3] Cannon, M.J. (2009). Congenital cytomegalovirus (CMV) epidemiology and awareness. Journal of Clinical Virology, 46 Suppl. 4, S6-10.

[4] Bate, S.L., and Cannon, M.J. (2011). A social marketing approach to building a behavioral intervention for congenital cytomegalovirus. Health Promotion Practice, 12(3) 349-360.

[5] Fowler, K. B., Stagno, S., and Pass, R. F. (1993). Maternal age and congenital cytomegalovirus infection: screening of two diverse newborn populations, 1980-1990. Journal of Infectious Diseases, 168(3), 552-556.

[6] Kenneson, A., and Cannon, M.J. (2007). Review and meta-analysis of the epidemiology of congenital cytomegalovirus (CMV) infection. Reviews in Medical Virology, 17(4), 253-276.

[7] Nyholm, J.L., and Schleiss, M.R. (2010). Prevention of maternal cytomegalovirus infection: current status and future prospects. International Journal of Women's Health, 2, 23-35.

[8] Fowler, K. B., Stagno, S., and Pass, R. F. (1993). Maternal age and congenital cytomegalovirus infection: screening of two diverse newborn populations, 1980-1990. Journal of Infectious Diseases, 168(3), 552-556.

CMV and prevention of maternal infection during pregnancy is low. Surveys indicate that between 14 and 22 percent of U.S. women have heard of CMV and few were familiar with prevention strategies. However, most of the women surveyed felt that CMV prevention guidelines would be "very" or "somewhat easy" to follow, and few felt they would be "very difficult".[9] In order to design and implement an effective behavioral intervention for congenital CMV, CDC needs additional information regarding the appropriate nature, depth, and scope of the prevention guidelines. Prevention guidelines, as well as information about CMV transmission, must be presented in such a way that audiences comprehend the messages, relate to them, remember them, and accept them.

This request for clearance is to conduct a multiphase communication research study to determine effective CMV communication strategies to reach the target audiences. The first phase will be largely exploratory and will include focus groups with Caucasian and African-American pregnant or expecting mothers ages 18-40 who also have a child age 5 years or younger. The focus groups will assess understanding of audience members' knowledge, attitudes, and beliefs about CMV, their perceptions about personal risk and prevention behaviors, their communication preferences, and initial reactions to CDC CMV messages and materials. The second phase will consist of a web survey to assess baseline awareness and knowledge regarding congenital CMV, measure current CMV prevention behaviors prior to viewing any CMV communication interventions (factsheet, video) and CDC's CMV prevention guidelines, and test refined CDC CMV messages and materials with a larger sample of the target audience.

1.1. Privacy Impact Assessment

I. Overview of the Data Collection System

This project will collect data in two phases. The first phase will include exploratory focus groups and the second phase will include a web survey. The overall goal of this project is to test the effectiveness of CDC CMV communication interventions and recommended guidelines for preventing congenital CMV with the target audiences. The target audiences for this research will include Caucasian and African-American pregnant or intending to get pregnant mothers ages 18-40 who also have a child age 5 years or younger. We detail each phase of research below.

Phase I

Phase I research will consist of eight (8) exploratory focus groups conducted to gain an understanding of audiences' knowledge, attitudes, and beliefs about CMV, their perceptions about personal risk and prevention behaviors, and their communication preferences. The focus groups will be conducted in two cities: Atlanta, Georgia, and San Diego, California. The overall goal for this phase will be to identify potential messaging frames for communicating information about congenital CMV to the target audiences and adopting CMV preventive guidelines as well as gather initial reactions to existing draft CMV communication interventions developed by CDC, including a one-page CMV factsheet (supplemental form) and a CMV video (not currently on CDC's website but available upon request). In addition, any cultural differences that may affect adoption of CMV prevention guidelines, message content and framing, and dissemination between the target audiences will be explored. Westat will work with professional focus group facilities in each city to identify and recruit participants for groups. The focus groups will be conducted with six to nine participants in each group and will last no more than 90 minutes. Participants will be asked to arrive early to complete a demographic profile questionnaire and consent form, each of which will take approximately 15 minutes to complete. See Table 1 for the focus group research design.

[9] Ross, D., Victor, M., Sumartojo, E., and Cannon, M.J. (2008). Women's knowledge of congenital cytomegalovirus: Results from the 2005 HealthStyles (TM) survey. Journal of Women's Health. 17, 849-858.

Table 1. Phase I Research Design

City	Target Audience	Number of groups
Atlanta, GA	Caucasian women ages 18-40 with children age 5 or younger and pregnant or planning to become pregnant in the next year.	2
	African-American women ages 18-40 with children age 5 or younger and pregnant or planning to become pregnant in the next year.	2
San Diego, CA	Caucasian women ages 18-40 with children age 5 or younger and pregnant or planning to become pregnant in the next year.	2
	African-American women ages 18-40 with children age 5 or younger and pregnant or planning to become pregnant in the next year.	2

The focus group data will be collected via the use of trained moderators and a structured moderator's guide will ensure that consistent data are collected across the groups. Upon completion of each focus group, the audiotapes and transcripts will be made available to Westat by the focus group facility in each city. Participant identifying information will be removed from the tapes before they are analyzed. All information gathered will be stored and maintained for the length of the project. Findings from Phase I will inform refinements to existing communication interventions. The finalized factsheet and video will be further tested in Phase II.

Phase II

Phase II research will include a web survey to (1) examine baseline awareness and knowledge regarding CMV, (2) assess baseline CMV prevention behaviors prior to viewing CMV communication interventions, (3) assess appeal and evaluate the impact of CMV communication interventions on their attitudes, beliefs, and behavioral intentions regarding prevention behaviors and (4) assess knowledge, attitudes and behaviors pre-and post-interventions with a larger target audience sample (N=800).

Similar to Phase I, target audiences for Phase II will consist of Caucasian and African-American women ages 18-40 who have a child age 5 or younger and are currently pregnant or planning to get pregnant in the next year. Participants will be recruited for the web survey in Phase II from a consumer panel using a pre-targeted variable to identify pregnant or intending to get pregnant women in this age group who also have a child age 5 years or younger. Harris Interactive will be responsible for recruiting participants, providing incentives using their panel incentive system and programming and hosting the web survey. The web survey will last approximately 11 minutes. Participants in each racial group will be randomly assigned to view one of two communication materials, either the CMV factsheet or the CMV video. The web survey will include some questions specific to the communication material they were assigned to view (either the factsheet or video). However most questions on the web survey relate to knowledge, attitudes, and beliefs pre and post materials presentation and will be similar across conditions. Web survey data will be collected through a secure online website hosted and maintained by Harris Interactive. De-identified survey data will be delivered to Westat for analysis purposes and then to CDC at the close of the project. Data will be retained for the length of the project and then destroyed under Westat's policies and procedures for data retention and destruction. See Table 2 below for Phase II research design.

Table 2. Phase II Research Design

	CMV Communication Materials		
Target Audiences	**Factsheet N=400**	**Video N=400**	**Composition**
Caucasian women with children age 5 or younger and pregnant or planning to become pregnant in the next year.	n=200	n=200	Females, Caucasian, education mix, mix of ages 18-40
African-American women with children age 5 or younger and pregnant or planning to become pregnant in the next year.	n=200	n=200	Females, African-American, education mix, mix of ages 18-40

The data collection system includes:

a) *Focus Group Screener* (Attachment 3A)
b) *Focus Group Discussion Guide* (Attachment 3B)
c) *Focus Group Demographic Profile Questionnaire* (Attachment 3C)
d) *Web Survey Screener* (Attachment 3D)
e) *Web Survey Screener Screenshots* (Attachment 3E)
f) *Web Survey: Factsheet Testing* (Attachment 3F)
g) *Web Survey: Factsheet Testing Screenshots* (Attachment 3G)
h) *Web Survey: Video Testing* (Attachment 3H)
i) *Web Survey: Video Testing Screenshots* (Attachment 3I)

II. Items of Information to Be Collected

Most focus group participants will come from an existing database (or list) of potential participants, owned and maintained by each focus group facility During the screening process for Phase I, the focus group facility will collect data on participants' name, race/ethnicity, age, education level, and whether they meet the screening criteria (Attachment 3A). This information will be used by the facility to schedule participants for the focus groups, and mail out a confirmation letter verifying the person's participation and provide the exact date, time and location of the focus group. Participants will be asked to arrive at the facility 30 minutes prior to the start of the focus group to complete a paper-and-pencil demographic profile questionnaire to verify the accuracy of the recruit (Attachment 3C) as well as a consent form (Attachment 4). Participants will only provide their first name during the focus group discussions and on the demographic profile questionnaire. The focus group discussion guide (Attachment 3B) will collect the following information:

- Knowledge and awareness about CMV
- Beliefs about CMV risk and exposure
- Attitudes about CMV prevention
- Perceptions about draft concepts about CMV
- Reactions to existing draft CDC CMV materials (factsheet and video)
- Communication preferences

The facility in each city will deliver participant demographic data to Westat and CDC after removing information in identifiable form (IIF) such as their last name, phone number, and address.

Screening criteria for the web survey in Phase II will be similar to the focus groups in Phase I (Attachment 3D). Harris Interactive will have access to personal identifying information of web survey participants since they are panel members. However, no personal identifying information will be included in the final dataset Westat

receives from Harris Interactive. Only de-identified survey data and demographic information included in the screener will be sent to Westat along with participant IDs. The web survey questions have been carefully crafted to collect the following information:

- Baseline awareness and knowledge regarding CMV
- Current CMV prevention behaviors prior to viewing communication interventions (factsheet or video)
- Appeal and impact of materials and messages on their attitudes, beliefs, and behavioral intentions regarding prevention behaviors, post-intervention
- Knowledge and perceived risk pre-and post- intervention

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 request.

A.2. Purpose and Use of Information Collection

The CDC's NCBDDD will fund two phases of research to determine most effective CMV communication strategies to reach the target audiences most at-risk for congenital CMV infection. The findings will help the CDC effectively communicate to and educate those most at-risk for CMV infection. Though CMV is more common than other well-known conditions such as Down syndrome or fetal alcohol syndrome, CDC has not conducted much research in the field of congenital CMV infection. There seems to be a troubling disconnect between its rate of occurrence and the public's awareness. This project is groundbreaking in the world of CMV research and the results will help educate women most at risk about the virus and inform them on easy, every day guidelines to keep their unborn babies safe. If the requested data collection was not conducted, CDC would be unable to test the effectiveness of CMV communication interventions with at-risk populations, a preventable virus that affects more than 5,500 children born each year. The collection of this information would enable CDC to build a basic toolkit of communication interventions that have been audience tested for acceptance, comprehension, and recall.

2.1. Privacy Impact Assessment Information

(i) Why the information is being collected

The overall purpose of this study is to assist CDC in their efforts to communicate about CMV to target audiences. As discussed in the Section 1.A Background, congenital CMV is more common than other well-known birth defects including Down syndrome, fetal alcohol syndrome, and neural tube defects. Little research has been conducted by CDC in this area. Currently, awareness about congenital CMV and prevention of maternal infection during pregnancy is low. In order to design and implement an effective behavioral intervention for congenital CMV, CDC needs additional information regarding the appropriate nature, depth, and scope of the prevention guidelines. Prevention guidelines, as well as information about CMV transmission, must be presented in such a way that at-risk audiences comprehend the messages, relate to them, remember them, and accept them.

(ii) Intended use of the Information

Intended uses of the focus group findings include the following: (1) CDC will be able to explore effective messaging frames for communicating about CMV and adopting prevention guidelines, (2) CDC will be able to better understand any cultural differences between the different racial segments, and (3) CDC will receive some initial reactions to the existing CMV materials including a factsheet and video and inform material refinements before testing with a larger sample.

Intended uses of the web survey data will be to inform CDC if the communication interventions (e.g., factsheet or video) are likely to increase knowledge of CMV, including the desired behaviors for adopting CMV prevention guidelines, if they are likely to influence attitudes about risky behaviors and motivate behavior change, and which format is most appealing to members of the target audience. Findings will also suggest appropriate dissemination channels for reaching the target audiences.

Impact on Privacy to Respondents: As noted in section A.1 above, no personal identifiable information collected will be transmitted to CDC. The only IIF being collected (respondent name, address, and phone number) is to be used by the focus group facilities (that will be hired by the contractor Westat) to screen potential respondents to determine eligibility for the focus groups. Although Harris Interactive may have access to the consumer panel member's IIF (name, address, phone number, email, etc.), they will use respondent's name for screening into the web survey but will not pass any IIF on to Westat at any point. Survey data plus limited demographic information will be delivered to Westat along with a participant ID. The participant ID will be non-identifying and will not be linked to any personal information that is delivered to Westat and CDC. Therefore, the proposed data collection will have little or no effect on the respondent's privacy.

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

The web survey in Phase II of this project will be conducted electronically on the internet. All survey responses (100%) will be submitted through a secure survey website established for this project. The website will be maintained by Harris Interactive. Minimum information will be collected from the respondents to ensure they are eligible for the survey and that there are an equal number of Caucasian (n=400) and African-American n=400) women represented in the sample. Web survey is a cost-effective way of surveying a large number of people. It allows respondents the flexibility of completing the survey at a time that is most convenient.

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

CDC has done some preliminary research on this topic to better understand the public's awareness of CMV, which is estimated to be quite low. Findings from the 2010 *HealthStyles* survey indicate that only 13% of American women have heard of congenital CMV. Moreover, it was ranked the lowest in awareness compared to all other childhood conditions asked about in the survey.[10] Authors suggest there is a great need to educate the public about congenital CMV and guidelines for preventing maternal infection during pregnancy. While CDC has developed CMV prevention messages for target audiences, no formative research has been conducted with target audiences. The proposed data collection is unique in that it will provide CDC with a basic toolkit that consists of core content that is well understood and has been audience tested from which CDC can eventually build upon. This data collection effort does not duplicate any past, current, or planned information collection by other federal government agencies. Findings will help inform the development of future communication materials about CMV that are understood, accepted, and remembered by the target audience.

10 Cannon M, Westbrook K, Levis D, Schleiss MR, Thackeray R, Pass RF. (2012). Awareness of and behaviors related to child-to-mother transmission of cytomegalovirus. Preventive Medicine 54(5):351-357.

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 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 test the effectiveness of CMV communication interventions with at-risk populations, a preventable virus that affects more than 5,500 children born each year. The collection of this information would enable CDC to build a basic toolkit of communication interventions that have been audience tested for acceptance, comprehension, and recall.

There are no legal obstacles to reduce the burden.

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

This request fully complies with regulation 5 CFR 1320.5. The web survey is not designed to produce results that can be generalized to the entire study population. Instead, the web survey results will be used to make comparisons of baseline and post-intervention knowledge of CMV and behavioral intentions in an effort to evaluate the effectiveness of the materials being tested.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the 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 February 24, 2012 (volume 77, number 37, pages 11125–11126). No substantive public comments were received in response to this notice.

B. Since October 2011, the CDC CMV team has collaborated with Westat staff on the development of data collection instruments for this study.

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

Two factors affect incentive amount for focus groups: the target audience being recruited and the facility location. To ensure our focus group costs were reasonably priced, we conducted a competitive analysis and contacted 3 facilities in the 2 cities (Atlanta, GA and San Diego, CA) we plan to conduct focus groups and requested bids. The incentive amount for this target audience across the 2 cities was fairly similar and ranged from $37.50 per hour in San Diego to $42.50 per hour in Atlanta. We feel confident offering this incentive amount is appropriate given the target audience of mothers, who will need to find childcare for their toddler in order to attend the focus group after work hours. The incentive will also facilitate recruitment of this harder to reach population. This target audience are often more difficult to recruit than more general audiences because in addition to getting themselves to the group during their precious evening hours, they also have to arrange for childcare in order to attend. Focus group facilities do not offer childcare services to participants due to liability concerns. Therefore, the incentive amount needs to, at the very least, help the participants cover outside childcare costs, if needed. It is assumed that the incentive offered for the groups will allow women to pay for their transportation costs to and from the facility, as well as help with the cost for off-site childcare. Research has consistently shown the value of offering remuneration for motivating respondents to participate in a research study: "Focus groups are unique from other data-gathering processes in terms of the investment that must be made by the individual. It is therefore no surprise that a tradition has been established to provide incentive for participation. From a practical aspect, it would be next to impossible to conduct focus groups without incentives in some situations. The incentive is not a reward and not really an honorarium or salary. It is an incentive. It serves as a stimulus to attend the session. The primary function of the incentive is to get the participants to show for the focus group—and to show up on time. The incentive serves to protect the promised time slot from being preempt."[11] The IRB approval of the study (Attachment 5) included the review and approval of this level of remuneration.

Web survey respondents will be recruited through a large consumer panel using a pre-targeted variable to identify pregnant or intending to get pregnant women in the targeted age group who also have a child age 5 years or younger by our partner, Harris Interactive. Their incentive for participating in the 11 minute survey will be handled through the panel's established incentive system. Harris Interactive typically offers Harris Interactive Points to their panel members for survey participation. These points can be redeemed for cash once members have accumulated a certain amount. The amount of the incentive is determined by the length of the survey and participants are aware of the incentive prior to agreeing to participate.

A.10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the NCBDDD Privacy Officer and determined that the Privacy Act does not apply. Westat will hire professional focus group facilities in each city to screen and schedule focus group participants. The only IIF that will be obtained are the participants' name, phone numbers, and mailing addresses for setting up interview appointments and mailing confirmation letters. This IIF will be maintained at the focus group facility in its proprietary files. These personal identifiers will not be linked to data. During the focus groups, only first names will be used. Focus groups will be audio taped and transcribed for use by the Westat research team in developing a report. The audio tapes will be stored in a locked file cabinet, accessible only to project staff. The recording will be destroyed at the end of the study, which is currently January, 2014.

Some demographic information will be collected from the web survey respondents, including gender, year of birth, education level, race/ethnicity, and household income range. Harris Interactive may have access to more personal identifying information on the consumer panel's members, but this is not something that is required for the purposes of this study. The web survey participants will not be asked to indicate their name or address

[11] Krueger RA, Casey MA. Focus groups. A practical guide for applied research. Thousand Oaks (CA): Sage; 2009.

in the survey. Harris Interactive will be responsible for ensuring they are paid appropriately, therefore no contact or mailing address information will be collected by Westat.

Institutional Review Board Approval: Westat's Institutional Review Board (IRB) reviewed the study instruments and granted approval for the study due to minimal risk (Attachment 5). The study was approved by the IRB on February 10, 2012.

10.1. Privacy Impact Assessment Information

A. The NCBDDD Privacy Officer has reviewed this submission and determined that the Privacy Act does not apply. Each focus group facility and the consumer panel that Harris Interactive will be recruiting from maintains its own list of individuals interested in participating in focus groups and surveys from which they will draw and recruit participants.

B. All data (hard copy and electronic) will be stored at Westat, CDC's selected contractor. All study materials (tapes and research notes) will be properly filed, maintained, and secured in a locked file cabinet. Electronic data will be kept on the project-specific network on Westat's secure server, which is accessible only to users granted rights by the project director and in a secure location with restricted physical access to staff working on the project only. Completed screener guides will be requested from the recruiting firms and destroyed by the research team once information collected from screener is moved to an aggregated form. Harris Interactive will provide Westat with weekly recruitment monitoring reports to ensure that a sufficient mix of Caucasian and African-American women in the targeted age group as well as a mix in education levels is represented in our final sample. These recruitment reports will include screening criteria but not participant names or any contact information.

C. An Informed Consent Form will be obtained from all of the participants participating in the focus group (Attachment 4). Consent forms will be signed before the focus group begins. Project staff will be available to answer any questions that the participants may have prior to the beginning of the focus group. The trained moderator will assure participants that any comments made during the focus group will not be attributed to them by name in any of the reports resulting from this research.

Further, the participants in both the focus group as well as the web survey will be reminded that their participation is voluntary and that they may withdraw from the study at any time. Should focus group participants decide to withdraw from the study, they will still receive their promised incentive. Web survey respondents will receive their incentive upon completion of the web survey. Focus group respondents will be informed during the screening process that all notes and transcripts from the data collection will solely be used to write the final report. All of the transcripts and notes from the focus groups will only be available to the project staff. In addition, this information will also be disclosed to the respondents in the informed consent form.

A.11. Justification for Sensitive Questions

There are no items considered to be highly sensitive for respondents. Potential participants will be asked about their pregnancy status during screening in both the focus groups and web survey. Web survey participants will be drawn from a large consumer panel using a pre-targeted variable to identify pregnant women or women intending to get pregnant, therefore the screening questions will be for confirmation purposes only. The focus group discussion protocol does not contain questions that ask participants to share any personal aspects of their

pregnancy with the group, and participants may refuse to answer any question they wish. Our target audience includes women ages 18-40 who are pregnant or planning to become pregnant in the next year and have a child age 5 years or younger. CDC wishes to get feedback from women most at risk for congenital CMV to better target health education materials and messages about CMV prevention guidelines.

A.12. Estimates of Annualized Burden Hours and Costs

For the focus groups, it is estimated that 144 respondents will have to be screened in order to recruit 72 participants. Each screening will take approximately 5 minutes. The estimated response burden for the screening process is 12 hours.

The focus groups will have an average of 9 participants each. Eight focus groups will be conducted in two cities (Atlanta, GA, and San Diego, CA) with a total of 72 participants. The demographic questionnaire (Attachment 3C) and informed consent (Attachment 4) will each take 15 minutes to complete; the focus group discussion using the moderator's guide (Attachment 3B) will take 90 minutes to complete. All focus group activities will have a total burden of 156 hours.

For the web survey, it is estimated that 4,800 respondents will have to be screened in order to recruit 800 participants. The respondents will be pre-screened and recruited after being asked some brief screening questions (Attachment 3D); the screening process should take approximately 3 minutes. The respondents will be recruited from an online consumer panel by our partner, Harris Interactive. They will use a pre-targeted variable to target Caucasian and African American women, ages 18-40, who are either pregnant or planning to get pregnant and have a child age 5 or younger. The estimated response burden for the screening process is 240 hours.

Web survey respondents will view one of two communication materials, either the CMV factsheet (n=400; Attachment 3F) or the CMV video (n=400; Attachment 3H). Within each type of communication material, equal number of African-American (n=200) and Caucasian respondents will be included. The web survey will take participants 11 minutes on average to complete for a total burden of 147 hours. The total burden for both Phases I and II is 543 hours.

Table A.12.A. Estimated Annualized Burden Hours

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Phase I: Focus Groups					
Women of childbearing age (ages 18-40)	Participant Screener	144	1	5/60	12
Women of childbearing age (ages 18-40)	Demographic questionnaire	72	1	15/60	18
Women of childbearing age (ages 18-40)	Informed consent form	72	1	15/60	18
Women of	Focus group	72	1	90/60	108

childbearing age (ages 18-40)					
Phase II: Web Survey					
Women of childbearing age (ages 18-40)	Participant screener	4,800	1	3/60	240
Women of childbearing age (ages 18-40)	Web Survey	800	1	11/60	147
TOTAL					**543**

The annualized cost burden is show in Table A.12.B. The mean hourly wage rate is based on the most recent (May 2010) National Occupational Employment and Wage Estimates for all occupations, published on the Bureau of Labor Statistics website which is $21.35.
See http://www.bls.gov/oes/current/oes_nat.htm#00-0000.

Table A.12.B. Estimated Annualized Burden Costs

Type of Respondent	**Form Name**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Phase I: Focus Groups				
Women of childbearing age (ages 18-40)	Participant Screener	12	$21.35	$256.20
Women of childbearing age (ages 18-40)	Demographic questionnaire	18	$21.35	$384.30
Women of childbearing age (ages 18-40)	Informed consent form	18	$21.35	$384.30
Women of childbearing age (ages 18-40)	Focus group	108	$21.35	$2,305.80
Phase II: Web Survey				
Women of childbearing age (ages 18-40)	Participant screener	240	$21.35	$5,124.00
Women of childbearing age (ages 18-40)	Web Survey	147	$21.35	$3,138.45
TOTAL				**$11,593.05**

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

There are no costs to respondents associated with either capital and startup efforts or operation and maintenance of services for this project.

A.14. Annualized Cost to the Government

The average annualized cost to the Federal Government to collect this information is $189,336.35 for the 2012 calendar year. The federal government personnel estimate is based on cost of the Federal Project Officer and two Co-Principal Investigators who are responsible for the management and oversight of the project (Table A.14).

Contractor costs include direct labor for development of instruments, data collection, analysis and reporting for Phase I and Phase II; other direct costs including subcontractors, travel, and facility rental, participant recruitment and incentives; and indirect costs such as fringe, overhead, general and administrative fees.

Table A.14.

		Task 1: Development of Instruments	**Task 2: Phase I Data Collection and Reporting**	**Task 3: Phase II Data Collection and Reporting**	**Total ($)**
Federal Government Personnel Costs	CDC Project Officer (GS-13 at 10% time)	--	--	--	$8,500
	CDC Co-Principal Investigator (GS-15 at 5% time)	--	--	--	$5,492.30
	CDC Co-Principal Investigator (GS-9 equivalent at 5% time)	--	--	--	$2,479.05
Contractor Direct Labor		$5,830	$15,437	$23,555	$44,822
Other Contractor Direct Costs	Subcontractors, travel, recruitment and focus group facility, incentives	$391	$24,840	$31,954	$57,185
Total Contractor Indirect Costs	Fringe, overhead, general and administrative, fee	$8,983	$25,740	$36,135	$70,858
Total Annualized Cost to Government					$189,336.35

A.15. Explanation 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 Phase I focus groups will begin within 1 month after OMB approval and Phase II will begin within 1 month of the completion of the Phase I report. The entire study will be completed within 12 months. See Table A16 below outlines the project time schedule by activity.

Table A.16 Project Time Schedule

Activity	**Time Schedule**
Phase I: Focus Groups	
Recruit Participants	1 month after OMB approval
Conduct 8 focus groups	3 months after OMB approval
Draft report of focus group findings	5 months after OMB approval
Final report of focus group findings	6 months after OMB approval
Phase II: Web Survey	
Finalize web survey	7 months after OMB approval
Field web survey	8 months after OMB approval
Draft report of web survey findings	11 months after OMB approval
Final report of web survey findings	12 months after OMB approval

Phase I Analysis Plan

At the conclusion of the focus groups, notes and audio recordings from the focus groups will be analyzed for common themes and divergent viewpoints among and between audiences. The analysis will inform any refinement to the materials needed before continuing with Phase II. A final report of the Phase I focus group findings will be completed within 6 months after OMB approval.

Phase II Analysis Plan

The main goals for the web survey include:

- Assess changes in baseline knowledge, attitudes and behaviors following presentation of CDC CMV communication materials (factsheet or video) by target audience and by target audience domains of interest[12].
- Assess the effectiveness and appeal of the CDC CMV communication materials (factsheet or video) by target audiences

[12] Domains of interest include African Americans and Caucasians. Data permitting , additional domains of interest could be defined, for instance, in terms of education (e. g. women with HS or less education v. women with at least HS education).

To achieve these goals, web survey data will be collected assessing two CMV communication materials (factsheet and video) across two target audience groups (African American women and Caucasian women ages 18-40 who are either pregnant or plan to get pregnant within the next 12 months, and have a child age 5 or younger). Within each target audience group, respondents will be randomly assigned to view either the factsheet or video communication intervention. Table 1 below represents the resulting research design.

Table 1. Phase II Research Design

Condition	Target Audience	Communication Material	N size
A1	Caucasian	Factsheet	200
A2	Caucasian	Video	200
A3	African American	Factsheet	200
A4	African American	Video	200

Respondents will be asked CMV knowledge questions at baseline (pre-intervention) and again after viewing the communication intervention they've been assigned to (factsheet or video). The effect of presentations on baseline knowledge of CMV will be estimated by comparing responses at baseline to responses after the presentation of CMV guidelines in factsheet or video formats.[13]

- Knowledge, attitude and behavior difference (D1) between baseline responses and *post-factsheet* responses measure factsheet effects for Caucasians in the A1 respondent group, and for African Americans in the A3 respondent group.
- Knowledge, attitude and behavior difference (D2) between baseline responses and *post-video* responses measure video effects for Caucasians in the A2 respondent group, and for African Americans in the A4 respondent group.
- The differential effect of factsheet and video presentations can be measured by comparing knowledge difference estimates D1 and D2 by race and overall.

Phase II Analysis Steps

Step 1. Data Preparation. Close-ended survey items will be examined for missing and invalid responses. Westat's proprietary Autoimpute[14] software will be used to impute invalid and missing values.

Step 2. Descriptive statistics. Categorical responses will be summarized overall, and by domain, using frequency tables. Between-domain differences will be tested for statistical significance using Chi-square statistics. For example, respondent familiarity with the CMV virus be summarized by level of CMV familiarity, and compared between the domains to determine if a statistically significant difference existed (at the conventional 5% level) between Caucasians and African Americans respondents.

For items with ordered response levels, such as the CMV familiarity item, cumulative logit models with domain membership indicator as the predictor variable[15] will be fitted to the data to assess the direction of the difference and to identify which domain indicated a higher level of CMV familiarity. For nominal variables, only

[13] Post-2nd-presentation differences (e. g. differences after seeing both the video and the factsheet in some order) measure the *effect of presentation order*. We believe that difference to be of limited interest since the target population will typically be exposed to only one of the presentation modalities.

[14] AutoImpute performs regression modeling by pooling all available variables, both external and internal, in the dataset and can handle many variables and very complex data structures in a time efficient manner.

[15] The cumulative logit models could be expanded to include other respondent characteristics. For example, some of the following variables educational attainment, marital status, age, number of children, income etc have been shown in prior research to affect awareness and knowledge measures.

the Chi-square test will be used since direction of difference is undefined for nominal variables. The resulting frequency tables address Goal I concerning baseline familiarity with and awareness of CMV and also the part of Goal II that is concerned with the appeal and acceptance of factsheet and video.

Step 3. Measuring Effectiveness of Communication Materials. If the factsheet or the video effectively communicated the intended information and CDC's guidelines, then baseline responses will shift in the desired direction after viewing the video or the factsheet. For example, disagreement with the statement 'My unborn baby is *not* at risk for CMV' will increase and agreement with the statement 'CMV can spread through saliva' will also increase between baseline and exposure. Individual differences between post-baseline and baseline responses provide a simple measure for assessing both the significance and the direction of communication effects.

For the purpose of power calculation, responses will be grouped as desirable or not desirable. For example, *strong agreement* or *agreement* with the statement 'CMV can be transmitted though a toddler's urine are both desirable, but *disagreement* or *strong disagreement*, are not desirable. The minimum detectable difference[16] between desirable baseline response proportions of 0.1, 0.2, 0.3, 0.4, and 0.5, and the corresponding follow-up response proportions were, respectively, about 0.11, 0.14, 0.16, 0.17, and 0.18. In other words, given a sample size of 125 respondents, the null hypothesis that the baseline proportion remained unchanged at follow-up would be rejected if the observed baseline proportion increased from 0.1 to a follow-up proportion of about 0.21 (= 0.1 + 0.11). For larger sample sizes, the minimum detectable difference range of 0.11-0.17 is reduced, respectively, to the range of 0.075 – 0.153 (N = 250) and to the range of 0.05-0.09 (N = 500).

Step 5. Factor Analysis. The online survey includes groups of strongly related items for assessing knowledge, behaviors, and intentions. It is likely that responses to these groups of related items will prove to be highly correlated such as, for instance, the responses to questions about hand washing frequency at baseline. Westat will use factor analysis to extract and identify independent latent components that account for much of the correlations of responses to related items, and investigate and elucidate the between-demographic-group and over-time differences in the patterns of association factor analysis is likely to uncover.

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

Not applicable. The OMB expiration date will be displayed.

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

There are no exceptions to the certification.

[16] Based on sample sizes estimated with two-sided level 0.05 tests using continuity-correction and requiring power = 0.8.