HHS/CDC/NCIPC
SUPPORTING STATEMENT FOR
OMB INFORMATION COLLECTION REQUEST

Part A

Randomized Controlled Trial of Routine Screening for Intimate Partner Violence

Supported by:

National Center for Injury Prevention and Control
Centers for Disease Control and Prevention

Government Project Officers:
Joanne Klevens, MD, Ph.D. Science Officer
dzk8@cdc.gov/ 770-488-1386
Jim Martindale, Public Health Advisor
jpm3@cdc.gov / 770-488-1389
National Center for Injury Prevention and Control
Division of Violence Prevention
Prevention Development and Evaluation Branch
4770 Buford Hwy, NE, MS K-60
Atlanta, GA 30341

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ABSTRACT

Intimate partner violence (IPV) occurs frequently and has serious health, economic, and social consequences. Given the seriousness of this problem, numerous professional and health care organizations have recommended routine screening of women for IPV by health care providers in primary care settings. However, recent systematic reviews of the literature have not found evidence for the effectiveness of screening to improve health outcomes for women exposed to IPV. We are proposing to conduct a randomized controlled trial to provide this evidence. The trial will recruit 3680 women in a public obstetrics, gynecology, and family planning clinic. Women attending this clinic tend to be African American and of lower socioeconomic status. For this study (the Main Study), women will be randomly allocated to one of three arms: (1) screened for IPV, and if disclosing IPV, provided information on available IPV services; (2) not screened and all receiving information on available IPV services; or (3) a control group that will not be screened nor receive information on available IPV services. All three arms will be assessed with a self-report measure for mental health, disability, and quality of life at baseline utilizing an audio-computer-assisted structured interview (A-CASI) and at a 12-month follow-up utilizing a computerized-assisted telephone interview (CATI). A pretest with 196 women in this same clinic will be conducted to test the enrollment, randomization, interview, and follow-up procedures; provide estimates for outcome measures and a potential mediator of outcomes (contact of IPV services); and establish the concordance between measures used at baseline (in the clinic) and at a one-week follow-up over the phone. The study arms of the Pretest, which vary slightly from those of the Main Study, are designed to accomplish these intermediate objectives. The results will be used to refine the measures, procedures, and sample size requirements for the Main Study. The results from the Main Study, the Randomized Controlled Trial, will guide CDC as well as other governmental agencies, professional and health care organizations, and women's advocate groups in formulating its recommendations and policies regarding routine screening.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

Intimate partner violence (IPV) is a significant public health problem. Nearly 25 percent of surveyed women in the U.S. report being physically and/or sexually assaulted by a current or former partner at some time during their life.[1] Almost 62% of adult women who are sexually assaulted have been so by an intimate partner.[2] IPV has a multitude of serious consequences that include death, physical injury, increased rates of physical illness, posttraumatic stress, increased psychological distress, depression, substance abuse, and suicide.[3] Children who witness IPV are also at increased risk for many behavioral problems, including aggressive behavior.[4]

Early studies documenting the experience of IPV suggested that abuse perpetrated by intimate partners tended to be repetitive and escalate in severity over time.[5] This research has been the basis for promoting early diagnosis and intervention. Health care providers appear to be well situated to identify IPV. Women come into contact with health care services routinely for a number of reasons such as prenatal care, family planning, cancer screening, and well baby care. Women experiencing IPV make more visits to primary care facilities than non-abused women.[6] For these reasons, various professional and health care organizations have recommended routine screening of women for IPV in primary care settings.[7,8,9,10,11,12, 13,14,15,16]

The US Task Force defines *screening* as a "preventive service in which a special test or standardized examination procedure is used to identify patients requiring special intervention".[17] Preventive services are carried out on *asymptomatic* persons, that is, individuals who lack clinical evidence of the target condition. Current standards for making recommendations on screening are based on the grounds of the burden of disease; the availability and acceptability of accurate screening tests; the availability and acceptability of effective treatment; and evidence that early treatment (during the asymptomatic period) produces better results than waiting for the appearance of symptoms and diagnosis.[18,19,20] As previously shown, there is clear evidence that IPV is prevalent and generates great medical and societal costs. There is also evidence for the availability and acceptability of accurate screening tests.[21] However, various systematic reviews of the literature have not found evidence for the effectiveness of screening to improve health outcomes for women exposed to IPV. [22, 23,24]

Whether resources offered to patients during the asymptomatic phase are utilized by victims, and is more efficient and effective than intervening when she seeks care for mental or physical symptoms or an injury need to be established. There is also little information on other potential positive and negative effects of screening. Screening may lead to greater awareness among

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[1] Tjaden, P. & Thoennes, N. Full Report of the Prevalence, Incidence, and Consequences of Violence Against Women. Findings from the National Violence Against Women Survey. Washington, DC: National Institute of Justice, 2000.

[2] Ibid., p. 44.

[3] Panel on Research on Violence Against Women, National Research Council. Understanding Violence Against Women. Washington, DC: National Academy of Science, 1997.

[4] Fantuzzo, JW & Lindquist, CU. The Effects of Observing Conjugal Violence on Children: A Review and Analysis of Research Methodology. Journal of Family Violence 1989; 4: 77-94.

women of the frequency and seriousness of IPV, or serve as validation of the problem, and increase knowledge of the availability of, referral to, and utilization of IPV services for victims. On the other hand, screening may also have adverse consequences. Qualitative studies have suggested that asking women about IPV may reinforce their feelings of being stigmatized and increase anxiety.[25] Women also report feeling disappointed in their health care providers' behavior, often finding the provider uninterested, uncaring, or uncomfortable.[26-27]

Authority for CDC's National Center for Injury Prevention and Control to collect this data is granted by Sections 301 and 391 (Part J) of the Public Health Service Act (42 U.S.C. 241) (Attachment A). This act gives federal health agencies, such as CDC, broad authority to collect data and do other public health activities, including this type of study.

A.2. Purpose and Use of the Information Collection

Based on the recommendations of a recent expert panel convened by the Centers for Disease Control and Prevention (CDC), Division of Violence Prevention, we are proposing to conduct a randomized controlled trial (RCT) which we will refer to as the Main Study from here on. The purpose of this trial is to establish the impact of screening on women's physical and mental health. A Pretest will be conducted initially to establish the feasibility and acceptability of different screening methods and the concordance of different data collection methods to refine the design of the Main Study. We expect the Pretest to be completed in the first nine months of the project period.

Based on the results of the Pretest, we will submit a Revision or Change Request to the OMB for review of any changes to the Main Study. We expect these changes to be minimal but might include adjustments to sample size estimates, the recruitment or follow-up procedures, or deletions of items on the questionnaires.

The Main Study will compare patients screened and referred to patients who will all receive referral information and to patients who will not be screened or referred as to their health, quality of life, disability, and utilization of health care services. The proposed project addresses the Division of Violence Prevention's Level 1 priorities to evaluate the efficacy and effectiveness of promising interventions to prevent involvement (i.e., perpetration, victimization) in intimate partner violence.

The findings from the Main Study will provide empirical evidence of the utility of screening for IPV on women's health and will guide CDC in formulating its recommendations regarding routine screening of IPV, as well as guiding other governmental agencies, professional and health care organizations, and women's advocate groups in formulating their policies on screening for IPV.

A.3. Use of Information Technology and Burden Reduction

Asking questions with a user friendly computer interface is relatively low cost, staff free, and can be programmed to screen opportunely; it is easy to use; and more easily introduced into the

patient care flow.[28] In addition, computer assisted surveys appear to achieve higher disclosure rates than self-administered questionnaires or face-to-face encounters for many sensitive health issues[29,30,31,32,33], including IPV[34- 35], is acceptable to patients and health care providers, and increases solicitation and recall of health advice.[36] Thus, in the Main Study, we will test the effectiveness of computerized routine screening utilizing audio-computer-assisted structured interview (A-CASI) technology.

(A-CASI) and computer-assisted telephone interviewing (CATI) software will be used to reduce respondent burden. The A-CASI program will be on touch-screen laptops placed in private kiosks or offices in an OBGYN clinic (the Fantus Clinic in Chicago which is the outpatient facility for John H. Stroger Hospital). The questionnaire has been written at a seventh grade reading level. However, a research assistant will be available should a respondent need assistance in using the computer or understanding a question. The A-CASI program will automatically randomize participants to one of the study arms. The program includes the text of the question wording, response category wording, and automatic programming of the skip patterns, range checks and other on-line consistency checks and procedures during the interview. This way the respondent only sees the questions she needs to answer. If the user does not complete the entire process when she starts, by using her unique study number, she will be able to restart the interview at the last completed question. If necessary, the laptop and printer are portable and can be moved from the kiosk to the health care provider's exam room and the interview completed while the patient waits for her provider.

The CATI program will be used to conduct follow-up of participants. Similar to the A-CASI, the program includes the text of the question wording, response category wording, and automatic programming of the skip patterns, range checks and other on-line consistency checks and procedures during the interview so the interviewer only asks the relevant questions. It also creates an automatic record of all dialings, tracks the outcome of each interviewing attempt, and documents reasons for refusal or termination.

Data collection and data entry occur simultaneously with the A-CASI and CATI data entry system and can be extracted and analyzed with existing statistical packages directly from the system speeding the processing and analysis of the data. The quality of the data is also improved because the systems automatically detect errors and insure that there is no variation in the order in which questions are asked.

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

A literature search conducted for the U.S. Preventive Services Task Force utilizing MEDLINE (1966 to December 2002), PsycINFO (1984 to December 2002), and CINAHL (1982 to December 2002) found no evidence of the impact of screening for IPV on women's health.[22] A more recent search of the years 2003-2006, utilizing the same main search headers employed by the USPSTF, has reached similar conclusions.[37] We conducted an additional search of MEDLINE for the 2007 up to the third week of February of 2007 for this support statement and did not identify any randomized controlled trials of the impact on screening on women's health. In sum, there is no evidence which indicates that screening and intervention for IPV as encountered in health care leads to improved health or decreased utilization of health services

among women exposed to IPV. The expert panel convened to analyze the need for this RCT did not identify any ongoing randomized controlled trial which would provide evidence on the effectiveness of screening for IPV.

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

Small businesses are not a part of the respondent universe.

A.6. Consequences of Collecting the Information Less Frequently

For the Main Study and Pretest, we propose collecting baseline information with an A-CASI in which the participant will be face-to-face with the computer. We propose collecting follow-up data with a CATI at one week in the Pretest and at 12 months for the Main Study. In the Pretest we will collect the same information twice with a one-week interval which will allow us to establish the concordance of these two modes of data collection. The one year follow-up in the Main Study will allow us to establish the impact or effectiveness of screening on women's health.

There are no legal obstacles to reduce the burden.

A major consequence of not conducting this study is the potential waste of resources in the health care system. Resources are currently being invested in promoting screening in the health care system (e.g., training of health care providers; development and institutionalization of screening tools, etc.). If screening does not make a difference in health status, these resources could be redirected towards more fruitful interventions.

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

This study will be conducted among patients attending the OB/GYN facilities at the Fantus Clinic, which is the outpatient facility of the John H. Stroger Jr. Hospital in Chicago. This is not a randomly selected sample and as such, the findings may not be generalizable to all patients attending OB/GYN facilities in the U.S. However, we believe the findings will be applicable to other women of reproductive age of lower socioeconomic status attending OB/GYN facilities in urban centers. The demographic information we will collect from participants will allow us to further characterize this sample and compare it to other population groups.

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

A.8.1. A 60-day notice to solicit public comments was published in the Federal Registrar (volume 71, No.144, page 42644) on July 27, 2006. Attachment C contains a copy of the notice. Attachment M contains copies of the two public comments received in response to the FRN.

A.8.2. On February 5, 2005, a panel of six experts in the areas of IPV and or epidemiological deign were convened to provide guidance in addressing the research question. Members of this panel were as follows:

Chang, Judy	412.641.6665 jchang@mail.magee.edu	Dept of Obstetrics, Gynecology and Women's Health U of Pittsburgh
Coker, Ann	713.500.9955 ann.l.coker.uth.tmc.edu	Department of Epidemiology University of Texas School of Public Health
Houry, Debra E	404.616.3181/285.4625 dhoury@emory.edu	Dept of Emergency Medicine Emory University
Joffe, Marshall	215.573.7395/718.544.1237 mjoffe@cceb.upenn.edu	Dept. Biostatistics and Epidemiology, U of Penn School of Medicine
Macmillan, Harriet	905.521.2100 x 74287 macmilnh@mcmaster.ca	Canadian PSTF
Rhoads, George	732.235.4352 rhoads@umdnj.edu	Environmental Epidemiology, Robert Wood Johnson Medical School
Runyan, Desmond K	919.843.8261 drunyan@unc.edu	University of North Carolina CB #7240 Chapel Hill, NC 27599-7240

The panel concluded that a RCT was the best design to address the question. Panel members were unaware of published or ongoing studies in which the research question was addressed using a no screen control group.

For this study, the following CDC staff and PIs in John H. Stroger Hospital's Collaborative Research Unit have been actively involved in developing the procedures and revising the questionnaires:

- Joanne Klevens, epidemiologist (dzk8@cdc.gov) phone: 770-488-1386
- Laura Sadowski, clinical epidemiologist (sadowski@cchil.org) 312-864-3646
- Romina Kee, senior attending physician (romina@mail.cchil.org) / (312) 864-3630

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

We estimate that on average a respondent will contribute between 28 and 40 minutes of her time: 13-16 minutes while at the clinic and then 17-22 minutes for a follow-up telephone interview. The questions we are asking are relatively sensitive as they deal with physical and mental health, quality of life, disability, and exposure to IPV. Given the sensitive nature of the questions and time involved, we propose compensating participants for their time and effort with a $20 certificate at time of enrollment in the Pretest, and with a $10 certificate at time of enrollment and $15 gift certificate at follow-up in the Main Study. This amount has been used in previous studies conducted at this site with acceptable response rates. Incentives in this amount have been shown to improve response rates among those of low socioeconomic status.[38]

A.10. Assurance of Confidentiality Provided to Respondents.

The CDC Privacy staff have reviewed this submission and determined that the Privacy Act applies to this data collection, which includes highly sensitive information. The applicable Privacy system notice is 09-20-0136, Epidemiologic Studies and Surveillance of Disease

Problems. Identifying information (name and phone numbers where participant can be reached) will be collected at baseline to establish contact for follow-up. However, only an identification number will link this information to the respondents' answers on the A-CASI and CATI and will not be stored in the same database to minimize the chances of inadvertent disclosure of sensitive personal information in identifiable form. All identifiers with the exception of the study identification number will be removed from the study chart once the follow-up interview is completed and linked to the baseline interview.

The contractor, The Kuskokwim Corporation (TKC) Integration Services has subcontracted with Dr. Laura Sadowski and her group at John H. Stroger Jr. Hospital's Collaborative Research Unit to implement the study and all of its security safeguards. Neither TKC or CDC personnel will have access to identifiable data. All the subcontractor's personnel in the Collaborative Research Unit at John H. Stroger Hospital, from research assistants to project director, will be required to sign privacy pledges (please see Attachment B). Signed consent forms and receipts of incentive payments will be kept in a locked file cabinet in a locked office, accessible only by the investigators and other research staff of the Collaborative Research Unit. Project staff will be vigilant of laptop computers while they are being used. Electronic files will be secured in computers that are password protected and will be kept in a locked office in the Collaborative Research Unit when not in use. The physical security of the data will be ensured by the location of file servers, tapes, and tape backup units in locked areas of the Collaborative Research Unit. Transferable media and other backup materials as well as contact information will also be stored in lockable file cabinets in the Collaborative Research Unit. All identifiers with the exception of the study identification number will be removed from the study file once the follow-up interview is completed and linked to the baseline interview. Only aggregate data analyses and reports are planned. Once data analyses are completed and the final report submitted and approved, all identifying information will be shredded.

The consent scripts (see Attachments D and E) clearly inform the respondent that the information provided will be maintained in a secure manner and not disclosed to anyone but the researchers conducting this study unless compelled by law. Both phases of this project (Pretest and Main Study) have been approved by CDC-IRB (1/22/07 and 1/30/07). Copies of IRB approvals are included in Attachment F.

Given the sensitive nature of the questions, key safeguards have been put into place. These include:

- Obtaining informed consent. Patients verified to be eligible for enrollment will undergo the process of informed consent with a trained research assistant (RA). The consent scripts have been written at a reading grade level of 7.5 and 8.0 (based on the Flesh-Kincaid Readability Test) for the Pretest and Main Study, respectively. The script will be read slowly to the respondents by the RA. In the consent script, the RA will describe the purpose, content, and length of the interview; alert the respondent that the survey contains sensitive questions but that the participant may choose not respond to any or all questions; assure the respondent that the information she provides will remain private, and that participation is voluntary (see consent scripts in Attachments D and E). Potential participants will be given an opportunity to ask questions or have something they did not understand clarified. Respondents will be given a toll free phone number to contact the

Primary Investigator (PI) in the event they have questions regarding the study or the agency and a toll free phone number for the CDC Human Research Protection Office if they wish information on their rights as human subjects. Patients who choose not to participate will receive the usual standard of care.

- Maintaining privacy: Data collection will take place at 2 separate locations within Fantus, Clinic: the 3rd floor OBGYN clinic and the nearby 4th floor family planning clinic. The clinic will either designate a private office or be equipped with two portable private kiosks containing a touch screen computer and printer. Women who are accompanied by a child >3 years of age who cannot leave the child with another caregiver in the waiting room or accompanied by their partner who refuses to separate from the woman will be excluded from the study. For follow-up, we will ask participants to provide us with a safe time and telephone number to call. We will let her know that we will identify ourselves as the Women's Health Study when we call. To minimize the risk that other household members might be present during the telephone interview, before initiating the interview but after reminding the participant of the objectives of the study and content of the interview, the respondent will be asked if she can speak comfortably at that time. The interviewer will also ask the respondent to say, "I am busy", if at any time during the interview they feel they are no longer able to speak openly and in private. Interviewers will be trained to detect signs that may indicate the respondent is uncomfortable in which case she will again ask if this is a good time to talk and if the respondent feels completely comfortable talking at that time. If there is any doubt, arrangements will be made to call back at a time suggested by the respondent.

A.11. Justification for Sensitive Questions

The surveys include questions on sensitive issues such as quality of life, disability, mental health, and utilization of health care and IPV services. (Please see Attachments H-K). Some respondents will also be asked questions on exposure to IPV. Information on age, pregnancy status, insurance status, race, and ethnicity will be extracted from information in the Cook County Bureau of Health Services Electronic Medical Record Database. This information is needed to address the core purpose of the study. Although there are many ways to ask these questions, we have selected measures that have been well validated and are widely used.

However, to minimize the risk that respondents should be upset by these questions, interviewers will be made aware of the sensitive nature of the questions during training and will be taught to respond empathetically, and if a respondent shows any signs of being upset or requests additional help, the interviewer will refer her to appropriate mental health services available through the Bureau of Health. If a woman screens positive for current intimate partner violence at enrollment, she will receive a referral to the on site Hospital Crisis Intervention Project that provides support and advocacy for victims of IPV. All participants will receive information on IPV services after the follow-up interview.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.1. Burden

Table A-12 details the annualized number of respondents, the average response burden per interview, and the total response burden for the baseline questionnaire and follow-up interview. Estimates of burden for the survey are based on simulated runs with staff answering each questionnaire. On average it required about 15 and 12 minutes for respondents to complete the baseline questionnaire at pretest and for the Main Study, respectively, and an average of 17 and 22 minutes to answer the follow-up questionnaires at pretest and in the Main Study. In the Pretest (year 1), we will approach a total of 210 women to establish eligibility (please see Eligibility Script in Attachment G) and recruit a total of 196. In the Main Study (years 2 and 3), we will approach an estimated total of 4600 women to establish eligibility and recruit 3680 (total). The annualized figures are presented in the table below. The annualized average response burden equals 717.7 hours.

Table A.12- Estimate of Annual Burden Hours.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. burden/ response (in hours)	Total burden (in hours)
Women Seeking Health Care Services	Eligibility Script for Pretest	70	1	1/60	1.2
	Baseline Questionnaire Pretest	65	1	15/60	16.3
	Follow-up Questionnaire Pretest (estimated 10% lost to follow-up)	59	1	12/60	11.8
	Eligibility Script for Main Study	1,533	1	1/60	25.5
	Baseline Questionnaire Main Study	1,227	1	17/60	347.6
	Follow-up Questionnaire Main Study (estimated 30% lost to follow-up)	860	1	22/60	315.3
				Total	717.7

When the A-CASI instruments are developed, the Quality of Life questions identified in Attachment L will be incorporated into the draft instruments identified as Attachments H, I, J, and K. For this reason, burden is not itemized separately for Attachment L.

A.12.2. Respondent cost

Survey respondents will be patients attending the OBGYN and family planning clinic at the Fantus Clinic in Chicago. The Clinic's clientele contains significant numbers of lower income,

un-insured and under-insured women. In the past year, 76.6% of the clinic's clientele were African American women, 12.8% were Hispanic women, 7.6% were non-Hispanic White women, and 3% were women of other origins (i.e., Asian, Pacific Islander or Native American).. Based on Census data, the median annual salary for African American women in the U.S. is estimated at $28,581 (or $13.74/hour); the median annual salary for Hispanic women in the U.S. is $24,030 (or $11.55/hour); the median annual salary for White non-Hispanic women is $32,678 (or $15.71/hour); and the median annual salary for women of Asian and other origins is $21,623 (or $10.40/hour). Based on the distribution of the clinic's clientele by race/ethnicity and the median hourly wages of each group, we estimated a weighted mean of the median wage for the whole sample of $13.50/hour which multiplied by the hourly burden for both questionnaires estimated above, results in a total annualized cost for respondents of $9,689.64 (total $29,068.92).

Table A.12. Annualized Cost to Respondents.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. burden/ response (in hours)	Avg. Hourly Wage	Total Cost
Women Seeking Health Care Services	Eligibility Script for Pretest	70	1	1/60	$13.50	$15.75
	Baseline Questionnaire Pretest	65	1	15/60	$13.50	$219.38
	Follow-up questionnaire Pretest (estimated 10% lost to follow-up)	59	1	12/60	$13.50	$159.30
	Eligibility Script for Main Study	1,533	1	1/60	$13.50	$344.93
	Baseline questionnaire Main Study	1,227	1	17/60	$13.50	$4,693.28
	Follow-up questionnaire Main Study (estimated 30% lost to follow-up)	860	1	22/60	$13.50	$4,257.00
					Total	$9,689.64

A.13. Estimates of Other Total Annul Cost Burden to Respondents or Recordkeepers.

Respondents will incur in no capital or maintenance costs.

A.14. Estimates of Annualized Cost to the Federal Government.

The annualized cost to the Government for this data collection is estimated at $482,067.00 based on total estimated costs of $1,446,200. The total estimated costs include CDC/NCIPC costs of $48,600; and total estimated contracted costs of the study (pretest and main study) of $1,398,000. The majority of costs will be incurred during years 2 and 3 in conjunction with data collection for the Main Study.

In the table below, the estimated costs associated with this data collection are presented in annualized form.

Table A.14. Estimated Annualized Cost to the Federal Government.

I.	CDC/NCIPC Personnel		
	• Personnel	$15,000	
	• Travel	$1,067	
	Subtotal, CDC/NCIPC		$16,067
II	TKC with Collaborative Research Unit at John H. Stroger Hospital in Chicago (contractual costs)		
	• Personnel	$383,329.67	
	• Equipment, Supplies, Other	$36,733.33	
	• Travel	$1333.33	
	• Consultants	$13333.33	
	• Contract administration	$31,270.33	
	Subtotal, Contractual Costs		$465,999.99
	Total Annualized Costs		**$482,066.99**

The costs for CDC/NCIPC personnel include **Salaries** for a Project Officer and Science Officer to assist with and oversee this data collection. Each of these is assigned for 10 percent time for the duration of the 2 contracts (3 years). Based on an annual salary of $75,000, this equates to $15,000 for each year. Costs related to the participation of CDC personnel also include **Travel** expenses for the project officer to conduct two site visits to Chicago at a cost of $1,600 each (total $3,200 or apx. $1,066 per year).

The study will be conducted through a contract with The Kuskokwim Corporation (TKC; a minority-owned small business) who will subcontract the Collaborative Research Unit at Stroger hospital. The costs of this contract include **Personnel** (project director and staff, field coordinator, A-CASI recruiters and CASI interviewers, technical support for A-CASI and CATI programs, and administrative support), **Equipment, Supplies, and Other expenses** (4 private kiosks and chairs, 4 touchscreen computers, 2 printers, A-CASI and CATI database software and hardware, participant compensation, training, and supplies), **Travel** (researchers from the

Collaborative Research Unit to Atlanta), **Consultants** (A-CASI programmer and statistician), and **Administrative Costs**.

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

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

A.16.1. Tabulation and Analysis Plan

Data will be extracted and analyzed with Statistical Package for the Social Sciences directly from the CASI or CATI systems.

Sample description and comparability across groups. Univariate and bivariate (i.e., measures of association) techniques will be used (e.g., frequencies, Fischer's exact, chi-square and t tests) as appropriate to cell size and type of variable to describe participants overall and in each group to establish potential differences on sociodemographic variables and baseline health status (QOL, disability, and mental health). We will present the following table:

Demographic characteristics and baseline status of overall sample and by intervention group

Sociodemographics	Screened & referred	Not screened & all referred	Not screened or referred (Control group)	TOTAL p
Mean age % Race/ethnicity % high school + % insured % asymptomatic BASELINE: Mean QOL (SD) Mean SRQ (SD) Mean # days disabled (SD) Mean # health visits (SD) FOLLOW-UP Mean QOL (SD) Mean SRQ (SD) Mean # days disabled (SD) Mean # health visits (SD)				

Differences between groups. In the Pretest, we will explore differences between groups as to rates of IPV, acceptability of screening and referral strategies, and their impact on recall and use of IPV services. In the Main Study, we will establish potential differences between groups using MANOVA as to means of quality of life, disability, mental health, and utilization of health care at the one-year follow-up after controlling for baseline status and demographics. We will run analyses of variance to establish between which groups and on what variables these differences correspond to.

Concordance of CASI v. CATI. The Pretest will establish concordance between the two health assessment methods (CASI v. CATI) combining assessments from all groups at recruitment and all groups at follow-up. The reliability of health status between the initial A-CASI administration and CATI administration one week later will be assessed.

A.16.2. Publications

We will develop and submit publications to peer-reviewed journals on the following topics:

- A comparison of four screening and referral strategies for Intimate Partner Violence;
- Concordance of A-CASI and CATI data collection for health measures;
- Characteristics of non-participants in screening for IPV;
- The impact of screening for IPV on women's health.

A.16.3. Time Schedule

The following table presents the project time schedule:

Activity	**Time schedule**
• Pre-test measures/procedures • Revise as needed • Submit revisions to OMB	1 month after initial OMB approval
• Provide revised instruments to Contractor	As soon as OMB approval for revisions is received
• Data collection for Pretest	1-6 months after final OMB approval
• Analyses of Pretest data	9 months after final OMB approval
• Submit request for changes to protocol for main study to IRB and OMB	10 months after final OMB approval
• Provide revised instruments/procedures to Contractor	As soon as OMB approval for revisions is received
• Baseline data collection for main study	1-12 months after IRB and OMB approval of revisions
• Follow-up data collection	12-24 months after approvals
• Data cleaning and analysis	25-36 months after approvals
• Manuscript writing and submitting reports for publication	37-48 months after approvals

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

No exemption is being sought.

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

No exemption is being sought.

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[5] Walker, LE. (1984). The Battered Woman Syndrome. New York: Springer.
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