Randomized Controlled Trial of Routine Screening
for Intimate Partner Violence

(OMB #0920-0761)
Revision

OMB INFORMATION COLLECTION REQUEST
SUPPORTING STATEMENT
Part A

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ABSTRACT

The Centers for Disease Control and Prevention (CDC) requests OMB approval of revisions to a currently approved collection entitled " Randomized Controlled Trial of Routine Screening for Intimate Partner Violence" (approved 01/24/2008; expiration date 01/29/2011). The proposed changes are a result of findings from the Pretest that showed high numbers of Spanish speakers at recruitment clinics, a higher prevalence of reported exposure to intimate partner violence (IPV), and redundancy of the 20-item mental health scale with other measures being used. As a result, we are requesting approval to extend trial inclusion criteria to Spanish speakers, a reduction in sample size, and deletion of a 20-question mental health scale. These last two changes will result in a decrease in burden to respondents. In addition, we are requesting an extension of three years to complete this information collection.

The overarching purpose of the information collection has not changed nor are there substantial changes to the study methods.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

This information collection request is for a Revision (and extension of expiration date) to OMB #0920-0761, entitled "Randomized Controlled Trial of Routine Screening for Intimate Partner Violence" (approved 01/24/2008; expiration date 01/29/2011). This activity is sponsored by the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS), and is authorized under Sections 301 and 391 (Part J) of the Public Health Service Act (42 U.S.C. 241) (Attachment A).

In this request for Revision with an extension of the expiration date, CDC requests OMB approval to implement changes to the following:
1) Characteristics of participants – Extend recruitment to Spanish speakers : OMB Clearance No. 0920-0761 approves only the inclusion of English speakers for this data collection. In the Pretest, we discovered and had to exclude a high number of Spanish speakers in the clinics where recruitment for this study is taking place. CDC would like to extend the opportunity to participate in this study to Spanish speakers. This will allow us to apply our findings to English and Spanish speakers, increasing the generalizability of the findings. This modification does not change the burden hours or costs as Latinos were included in our estimates of the burden.

2) Number of participants – Reduction in sample size: OMB Clearance No. 0920-0761 approves a sample size of 3876 women for the RCT's Main Study. This sample size was based on previous studies' findings of a prevalence of 13% of women in primary care clinics reporting IPV in the past year. However, our pilot test showed that about 20% of women attending the clinics where we are recruiting reported IPV in the past year. With this higher prevalence, only 2675 women will be required for the Main Study. Together with the respondents from the Pretest, the total number of respondents for this information collection would be 2869.

3) Modification of data collection instrument – Deletion of mental health scale: OMB Clearance No. 0920-0761 approved the use of a 20-item scale to assess mental health. In the Pretest, participants found some of the items to be redundant with items in the Quality of Life scale also being used in this information collection. This Quality of Life scale also approved by OMB Clearance No. 0920-0761, has a mental health subscale as well as a physical health subscale, it showed good reliability and is reported to be sensitive to change while the 20-item mental health scale's sensitivity to change is unknown. As a result, CDC is requesting approval to delete the 20-item mental health scale.

4) Extension of expiration date: OMB Clearance No. 0920-0761 approval was given for 36 months and expires January 30, 2011. To date, we have collected and analyzed data for the Pretest, and based on the Pretest findings, have revised consent scripts and questionnaires and translated these into Spanish. These revisions have been approved by CDC and local IRBs. However, in order to allow sufficient time for the two data collections planned (baseline and one-year follow-up), CDC is requesting an extension of the expiration date for an additional three years.

Privacy Impact Assessment

Overview of the data collection system
Audio-computer-assisted structured interview (A-CASI) technology will be used to collect information at baseline and computer-assisted telephone interviewing (CATI) will be used to collect information at the one year follow-up. Medical records will be used for some parts of this information collection. We have contracted with the Collaborative Research Unit at John H. Stroger Hospital in Chicago for this information collection. Information collected will be maintained until data analyses are completed and the final report submitted and approved, all identifying information will be shredded.

Items of information to be collected
This information collection will include self-reported exposure to intimate partner violence, quality of life, days unable to work, utilization of health services outside the network of Chicago's Cook County Bureau of Health Services, and level of education. Medical records will be used to establish utilization of services within Cook County Bureau of Health Services, health insurance coverage, age, and race/ethnicity. Name and telephone numbers where participants can be reached will also be collected at baseline to be able to re-establish contact at the one-year follow-up.

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. Section A.10. describes in more detail how information will be maintained and de-identified.

Identification of website(s) and website content directed at children under 13 years of age
This information collection does not involve websites.

A.2. Purpose and Use of the Information Collection

Intimate partner violence (IPV) is a significant public health problem. Early studies documenting the experience of IPV suggested that abuse perpetrated by intimate partners tended to be repetitive and escalate in severity over time.[1] This research has been the basis for recommendations to screen promoted by multiple professional and health care organizations have recommended routine screening of women for IPV in primary care settings.[2,3,4,5,6,7, 8,9,10,11] However, various systematic reviews of the literature, including one conducted by the US Preventive Services Task Force, have not found any evidence for the effectiveness of screening to improve health outcomes for women exposed to IPV. [12, 13,14] The randomized controlled trial (RCT) proposed in this information collection request is being conducted to provide evidence for or against the effectiveness of routine screening to improve health outcomes for women exposed to IPV.

The three-arm RCT will compare patients screened and referred if positive to patients who will not be screened but will universally receive referral information and to patients who will not be screened or referred as to their quality of life, disability, and utilization of health care services. The proposed project addresses the CDC's Division of Violence Prevention's Level 1 priorities

to evaluate the efficacy and effectiveness of promising interventions to prevent IPV perpetration or victimization. The data collection has been funded through a fixed price.

The findings from this information collection 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.

Privacy Impact Assessment

(i) why this information is being collected

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.[15] Almost 62% of adult women who are sexually assaulted have been so by an intimate partner.[16] 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.[17] Children who witness IPV are also at increased risk for many behavioral problems, including aggressive behavior.[18]

Early studies documenting the experience of IPV suggested that abuse perpetrated by intimate partners tended to be repetitive and escalate in severity over time.[19] 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.[20] For these reasons, various professional and health care organizations have recommended routine screening of women for IPV in primary care settings.[21,22,23,24,25,26, 27,28,29,30]

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".[31] 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.[32,33,34] 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.[35] 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. [36, 37,38]

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 needs to be established. There is also little information on other potential positive and negative effects of screening. Screening may lead to greater awareness among 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.[39] Women also report feeling disappointed in their health care providers' behavior, often finding the provider uninterested, uncaring, or uncomfortable.[40-41]

This information collection conducted with a RCT design will provide evidence for or against the effectiveness of routine screening to improve health outcomes for women exposed to IPV as well as information on whether screening is associated with greater awareness among women of the frequency and seriousness of IPV, or increased knowledge of the availability and utilization of IPV services for victims of IPV.

(ii) the intended use of this information
The findings from this information collection 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.

(iii) information in identifiable form
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 data collection systems (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, and before transmission to CDC. Please see section A-10 for in-depth description on the strategies used to maintain data security.

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.[42] 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[43,44,45,46,47], including IPV[48- 49], is acceptable to patients and health care providers, and increases solicitation and recall of health advice.[50] Thus, in this information collection, we will test the effectiveness of computerized IPV screening utilizing audio-computer-assisted structured interview (A-CASI) technology. Impact of IPV screening will be assessed by collecting information on health at a one-year follow-up using computer-assisted telephone interviewing (CATI).

A-CASI and CATI software both reduce respondent burden. The A-CASI program will be on touch-screen laptops placed in private kiosks or offices in women's health clinics in Chicago. 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.[51] CDC conducted a literature search for 2007-August, 2009 identified one randomized controlled trial assessing the impact of screening on women's health, however, methodological issues encountered in this trial rendered its findings inconclusive.[52] In sum, there is still no evidence indicating whether screening and referral for IPV as encountered in health care leads to improved health or decreased utilization of health services among women exposed to 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 this study, there will be two data collection points: (1) for baseline information with an A-CASI in which the participant will be face-to-face with the computer and (2) for follow-up data

with a CATI at 12 months 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 women's health clinics in the Cook County Bureau of Health Services in Chicago. This is not a randomly selected sample and as such, the findings may not be generalizable to all patients attending women's health clinics in the U.S. However, we believe the findings will be applicable to other women of lower socioeconomic status attending women's health clinics 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 on the Revision and Extension was published in the Federal Registrar: Volume 74, Page Number 66976, of Publication Date 12/17/2009. Attachment B contains a copy of the notice. One public comment was received in response to the 60-day Federal Register Notice, but was nonsubstantive in nature – **ATTACHMENT H.**

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	215.573.7395/718.544.123 7 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 John H. Stroger Hospital's Collaborative Research Unit in Chicago 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.

Based on the Pretest, respondents contribute on average 66 minutes of their time: 28 minutes while at the clinic and then 38 minutes for the follow-up telephone interview. The questions we are asking are relatively sensitive as they deal with quality of life, disability (days lost from work), utilization of health services, and exposure to IPV. Given the sensitive nature of the questions and time involved, we proposed compensating participants for their time and effort with a $10 certificate at time of enrollment and $15 gift certificate at follow-up. However, based on the findings of the Pretest, we submitted a Request for Change that was approved by OMB on 01/22/09 to increase payment to respondent from $10 to $20 for the baseline assessment. By paying this amount at time of enrollment we were able to obtain an 82% participation rate in the Pretest. This amount was also considered a fair amount for study visits of this type by the Cook County Bureau of Health Services Institutional Review Board (personal communication with IRB member December 1, 2008). In addition, incentives in this amount have been shown to improve response rates among those of low socioeconomic status.[53]

A.10. Assurance of Confidentiality Provided to Respondents.

Identifying information (name and phone numbers where participant can be reached) will be collected by the contractor 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. Data will be transmitted to CDC de-identified.

John H. Stroger Jr. Hospital's Collaborative Research Unit (specifically, Dr. Laura Sadowski and her group) has been contracted to implement the study and all of its security safeguards. CDC personnel will not 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. 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 script (see Attachment C) clearly informs 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). IRB status for the Pretest has now been closed. A current copy of the IRB approval for the Main Study is included in **Attachment D**.

Privacy Act Impact Assessment Information

A. 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.

B. Various technical, physical, and administrative controls are used to secure the information collected. These include:

1. Technical: a Windows-based Active Directory schema restricts access to information to authorized users; authorized users may only gain access with a user ID and password; electronic procedures terminate a session after 30 minutes of inactivity, through use of a password-protected screen saver; Cook County Bureau of Health Services Hospital Information Systems have implemented a VPN to encrypt and decrypt information transmitted off-campus; information transmitted within the Cook County Bureau of Health Services campus the data is protected by 1 physical firewall (CISCO PIX 2500) and 1 software firewall (Internet Security and Acceleration Server) that prevent traffic of data outside its perimeter; the Collaborative Research Unit keeps an access log record and examines activity in information systems that contain or use electronic protected health

information; all computers have anti-virus and malware scanning software installed and updated to guard against, detect and report malicious software affecting IPV Stations and Servers.

2. Physical: Participating clinics either designate a private office or are equipped with two portable private kiosks containing a touch screen computer and printer which are collected at the end of each day; computers are kept inside locked closets; the Project Coordinator maintains a record of the movements of computers and any person responsible for the move; all study staff are identified with badges; ID badges are only issued after an employee clearance process; the information collected is kept in centralized servers within Stroger Hospital's Data Center facility; to ensure data integrity, the data are only temporarily kept in local hard drives until it is successfully transmitted to the study's database server; before any hard-drive is salvaged, the Collaborative Research Unit technical personnel physically perforate the hard drives; the Collaborative Research Unit IT Director oversees the movement, receipt and removal of all hardware and electronic media on an as-needed basis; Collaborative Research Unit personnel re-format and reinstall the operating system to ensure the removal of electronically protected information from the computers before they are made available for re-use; the Collaborative Research Unit IT Director oversees the erasure of any electronic media prior to reuse, as applicable;

3. Administrative: the Collaborative Research Unit's IT Director is officially responsible for the development and implementation of the information security policies and procedures required by law; the IT Director determines who is authorized and who supervises staff who work with electronic protected information or in locations where it might be accessed and to determine that the access of a workforce member to electronic protected health information is appropriate; the IT Director notes and reports security problems to the study PI; if a security issue is identified, through monitoring, reporting of possible issues, investigations, or otherwise, the IT Director has the responsibility and authority to take or direct appropriate action to address that issue; corrective action is reported in the next weekly scheduled research study meeting; corrective actions will be designed to ensure that the specific issues are addressed and similar problems do not occur in the future; staff are trained in the importance of protecting electronic information, the computer equipment, applications, and security threats, and sign a confidentiality agreement during the employee clearance process before an ID badge is issued and user IDs are assigned; when staff leave the project or should no longer have access to protected information as determined by the Principal Investigator, that employee's access to electronic information is terminated by disabling his or her user ID from the Unit's Active Directory and IPV databases; when a new session of the A-CASI software is initiated, the IPV information system automatically creates an entry with the time, the user, and the location of the session; the Collaborative Research Unit conducts periodic and thorough assessments of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected information held in the study computers and servers; when a member of the study leadership committee believes any risks exist, it is discussed and addressed on the scheduled weekly meeting; the Collaborative Research Unit has implemented security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with the HIPAA Security Rule; the Collaborative Research Unit regularly monitors usage of computer stations by observing access log files and suspicious inappropriate access to the Servers;

The Collaborative Research Unit backs up its computer systems regularly into a dedicated backup server located in the Data Center highly-secured facilities according to the following schedule:

Server Backups	Frequency	Type of Backup	Retention Period	Location
All network drives	Daily	Incremental	One Week	Data Center
All network drives	Weekly	Full	One Month	Data Center
All network drives	Monthly	Full	Two Months	Data Center
SQL Database Backup – Trans Logs and Backup files for SQL	Daily	Incremental & Full	Two months	Data Center
Websites	Daily	Incremental & Full	Two months	Data Center

Should an emergency or other occurrence (for example, fire, vandalism, system failure, human error, and natural disaster) damage IPV's systems that contain electronic protected information, the Collaborative Research Unit IT Director is responsible for restoring the system to its last operational state using the data previously backed up in the backup servers; the IT Director tests this procedure monthly, to ensure that data can be backed up, restored and operational as soon as possible.

C. Obtaining informed consent. Patients verified to be eligible for enrollment undergo the process of informed consent with a trained research assistant (RA). The consent scripts have been written at a reading grade level of 8.0 (based on the Flesh-Kincaid Readability Test) for Main Study. The script is read slowly to the respondents by the contractor's interviewers. In the consent script, the interviewers 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 to respond to any or all questions; assure the respondent that all identifying information will remain private to the extent allowed by law, and that participation is voluntary; and inform the respondent that the information collected will help in selecting better ways to ask women in clinics about their health (see consent scripts in Attachment C). 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 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.

D. In the informed consent script, participants are informed of the voluntary nature of their participation and that they can drop out of the project at any time without penalty. They are also informed that their answers will not have their name on them but will be identified

with a code number to keep their answers separate from everybody else's; that their answers to these questions will not be shared with anyone outside of the study team and will be kept private as much as allowed by law. Patients who choose not to participate will receive the usual standard of care.

A.11. Justification for Sensitive Questions

The interview include questions on sensitive issues such as race/ethnicity, level of education, quality of life, disability, utilization of health care and IPV services, and exposure to IPV. (Please see Attachments E-F). Information on age and insurance status 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 in Cook County Bureau of Health Services. If a woman screens positive for current IPV at enrollment, she will receive a referral to the Hospital Crisis Intervention Project at Stroger Hospital or to other available IPV services in her community that provide 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

The revisions requested will reduce 410 annual burden hours. Deletion of the mental health scale will reduce the burden response by 2 minutes; the reduction of sample size will reduce number of respondents; and extension of information collection time will decrease annualized burden. The Pretest has already been conducted and the estimates of burden for the interview in the Main Study are based on results from the Pretest. Based on our new sample size estimates adjusted as a result of findings in the Pretest, in the Main Study, we will approach an estimated total of 3340 women to establish eligibility and recruit about 2675 (total) women. The annualized figures are presented in the table below. The annualized average response burden equals 308 hours, which is a reduction of 410 burden hours.

Table A.12.1- Estimate of Annual Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. burden/ response (in hours)	Annual burden (in hours)
Women Seeking Health Care Services	Eligibility Script for Pretest	70	1	1/60	1
	Baseline Questionnaire Pretest	65	1	15/60	16
	Follow-up Questionnaire Pretest	59	1	12/60	12
	Eligibility Script for Main Study	668	1	1/60	11
	Baseline Questionnaire Main Study	535	1	16/60	143
	Follow-up Questionnaire Main Study (estimated 30% lost to follow-up)	356	1	21/60	125
				Total	308

A.12.2. Respondent cost

Survey respondents will be patients attending women's health clinics in the Cook County Bureau of Health Services in Chicago. These clinics attend significant numbers of lower income, un-insured and under-insured women. About 76.6% of the clinics' 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 all questionnaires, results in a total annualized cost for respondents of $4,152.83.

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
	Eligibility Script for Pretest	70	1	1/60	$13.50	$15.75

Women Seeking Health Care Services						
	Baseline Questionnaire Pretest	65	1	15/60	$13.50	$219.38
	Follow-up questionnaire Pretest	59	1	12/60	$13.50	$159.30
	Eligibility Script for Main Study	668	1	1/60	$13.50	$150.30
	Baseline questionnaire Main Study	535	1	16/60	$13.50	$1926.00
	Follow-up questionnaire Main Study	356	1	21/60	$13.50	$1682.10
Total						$4,152.83

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

Respondents will incur in no capital or maintenance costs.

A.14. Annualized Cost to the Federal Government.

Two types of government costs will be incurred: (1) government personnel and travel costs, and (2) contracted data collection.

1. NCIPC has assigned 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 information collection (3 years). Based on an annual salary of $90,000, this equates to $18,000 for each year (total $54,000) for cost of government personnel. Over the contract project period, government personnel will also conduct two site visits to Chicago at a cost of $1600 each (total $3200 or $1066.67 per year).
2. The Collaborative Research Unit at John H. Stroger Hospital has been contracted to collect the information for the Main Study for a cost of $1,369,468.00.

Therefore, the annualized cost for the Government for this data collection is estimated at $475,556 (total $1,426,668 over 3 years).

A.15. Explanation for Program Changes or Adjustments

The proposed changes are based on findings from the Pretest that showed high numbers of Spanish speakers at recruitment clinics, a higher prevalence of reported exposure to intimate partner violence (IPV), and redundancy of the 20-item mental health scale with other measures being used. As a result, we are requesting approval to extend trial inclusion criteria to Spanish

speakers, a reduction in sample size based on the higher prevalence of exposure to IPV, and deletion of the 20-item mental health scale.

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 A-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, baseline and follow-up 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 + % uninsured % asymptomatic BASELINE: Mean Quality of Life (SD) Mean # days disabled (SD) Mean # health visits (SD) FOLLOW-UP Mean Quality of Life (SD) Mean # days disabled (SD) Mean # health visits (SD)				

Differences between groups. In the Pretest, we explored 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 ANOVA 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 A-CASI v. CATI. The Pretest will establish concordance between the two health assessment methods (A-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 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**
• 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, analyses, manuscript development	25-36 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 exception is being sought.

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