

## Supplementary Online Content

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### **Trial Protocol**

This supplementary material has been provided by the authors to give readers additional information about their work.

# Randomized Controlled Trial of Routine Screening for Intimate Partner Violence

## PROTOCOL

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*PROJECT OVERVIEW*

Title: Randomized Controlled Trial of Routine Screening for Intimate Partner Violence

Protocol Summary:

Although screening for intimate partner violence (IPV) has been widely recommended by multiple professional and health care organizations, recent systematic reviews of the literature have not found evidence for the effectiveness of screening to improve health outcomes for women exposed to IPV.

In this protocol, we propose conducting a randomized controlled trial with three arms to establish the impact of screening and referral to services for women disclosing exposure to IPV. In the first arm, participants will be screened, and if disclosing IPV, will receive information on available resources in the community. In arms two and three, participants will not be screened, but one group will receive information on available resources in the community and the other will not. All three groups will be assessed for disability, quality of life, and utilization of health care and IPV services at baseline and at a 12 month follow-up. Utilization of health care and mortality will be assessed at a three-year and two-year follow-up, respectively.

Investigators: Joanne Klevens, MD, Ph.D.

Principal investigator

NCIPC/DVP/Prevention Development and Evaluation Branch

[dzk8@cdc.gov](mailto:dzk8@cdc.gov) (e-mail) / (770) 488-1386 (phone)

Laura Sadowski, MD, MPH

Co-Director, Collaborative Research Unit, Cook County Hospital

Associate Professor, Department of Internal Medicine, Rush Medical

College, Chicago

[sadowski@cchil.org](mailto:sadowski@cchil.org) / (312) 864-3646

Romina Kee MD, MPH

Senior Investigator, Collaborative Research Unit and Department of

Obstetrics and Gynecology, John H. Stroger Hospital, Chicago

[romina@mail.cchil.org](mailto:romina@mail.cchil.org) / (312) 864-3630

William Trick, MD

Senior Investigator, Collaborative Research Unit and Department of

Obstetrics and Gynecology, John H. Stroger Hospital, Chicago

[wtrick@cchil.org](mailto:wtrick@cchil.org) / (312) 864-3631

Collaborators: Jim Martindale/Colby Moseley  
Project Officer

NCIPC/CDC/DVP/ Prevention Development and Evaluation Branch  
[Wei4@cdc.gov](mailto:Wei4@cdc.gov) / 770-488-3785

Diana Garcia, MPH  
Research Evaluation Coordinator, Collaborative Research Unit  
[dgarcia@cchil.org](mailto:dgarcia@cchil.org) / 312-864-3645

Francisco Angulo, MBA  
Director, Information Technology, Collaborative Research Unit  
[fangulo@cchil.org](mailto:fangulo@cchil.org) / 312-864-1410

Roles: Joanne Klevens conceptualized the study and overall design. Joanne Klevens, Laura Sadowski, Romina Kee, and William Trick have collaborated in refining the study design and selecting the measures, will conduct the pilot test of the measures and procedures, and will continue to collaborate in data analysis and publications. Laura Sadowski will coordinate the on-site research team and have overall responsibility for study implementation including training of field staff and budget management. Romina Kee has primary responsibility for local human subjects' applications and progress reports, will co-lead the training of OB/GYN providers and field staff, and has direct supervision of implementation of the field staff and health care providers. Romina Kee will serve as the Obstetrics & Gynecology lead for study activities and will assist in supervising the implementation of study procedures by OB/GYN providers. Dr. Trick will be liaison between the technology development, support team, and principal investigators. Diana Garcia will supervise research assistants in recruitment of participants and consent and interview procedures, and conduct field observations and debriefings to check for study fidelity.

# RANDOMIZED CONTROLLED TRIAL OF ROUTINE SCREENING FOR INTIMATE PARTNER VIOLENCE

## *INTRODUCTION*

### Definitions

In this proposal, *intimate partner violence* (IPV) refers to the intentional use (or threat of use) of physical or sexual violence, or emotional/psychological abuse (including coercive tactics) by a current or former spouse or dating partner.

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”.<sup>1</sup> Preventive services are carried out on *asymptomatic* persons, that is, individuals who lack clinical evidence of the target condition.

### Justification

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.<sup>2</sup> Almost 62% of adult women who are sexually assaulted have been so by an intimate partner.<sup>3</sup> 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.<sup>4</sup> Children who witness IPV are also at increased risk for many behavioral problems, including aggressive behavior.<sup>5</sup>

Early studies documenting the experience of IPV suggested that abuse perpetrated by intimate partners tended to be repetitive and escalate in severity over time.<sup>6</sup> 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

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<sup>1</sup> US Preventive Services Task Force. Guide to Clinical Preventive Services (3<sup>rd</sup> Edition). Baltimore, MD: Williams & Wilkins, forthcoming publication.

<sup>2</sup> 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.

<sup>3</sup> Ibid., p. 44.

<sup>4</sup> Panel on Research on Violence Against Women, National Research Council. Understanding Violence Against Women. Washington, DC: National Academy of Science, 1997.

Campbell JC. Health consequences of intimate partner violence. *Lancet* 2002;359:1331-1336.

<sup>5</sup> 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.

<sup>6</sup> Walker, LE. (1984). *The Battered Woman Syndrome*. New York: Springer.

care facilities than non-abused women.<sup>7</sup> For these reasons, various professional and health care organizations have recommended routine screening of women for IPV in primary care settings.<sup>8,9,10,11,12,13, 14,15,16,17</sup>

Current standards for making recommendations on screening for a condition 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.<sup>18,19,20</sup> 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.<sup>21,22</sup> 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.<sup>21,22, 23,24</sup>

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<sup>7</sup> Plitcha, S. The effects of woman abuse on health care utilization and health status: A literature review. *Women's Health issues* 1992; 2: 154-163.

<sup>8</sup> American Academy of Family Physicians (AAFP) Commission on Special Issues and Clinical Interests. *Family Violence: an AAFP white paper*. *Am Fam Physician* 1994; 50: 1636-46.

<sup>9</sup> American Academy of Pediatrics committee on Child Abuse and Neglect. The Role of the Pediatrician in recognizing and intervening on behalf of abused women. *Pediatrics* 1998; 101:1091-2

<sup>10</sup> American College of Emergency Physicians: Emergency medicine and domestic violence. *Ann Emerg Med* 1995; 25: 442-3.

<sup>11</sup> American College of Obstetricians and Gynecologists (ACOG) Domestic Violence. *ACOG Tech Bull* 209. Washington, DC: ACOG, 1995.

<sup>12</sup> American College of Nurse Midwives. Position statement on violence against women. Washington, DC: American College of Nurse Midwives, August, 1997.

<sup>13</sup> American Dental Association. Position statement on family violence. Chicago, IL: American Dental Association, December, 1996.

<sup>14</sup> American Nursing Association. Position statement physical violence against women. Washington, DC: American Nursing Association, September, 1991.

<sup>15</sup> Council on Scientific Affairs, American Medical Association. Violence against women: relevance for medical practitioners. *JAMA* 1992; 267: 3184-9.

<sup>16</sup> Emergency Nurses Association. Position statement: domestic violence. Park Ridge, IL: Emergency Nurses Association, 1994.

<sup>17</sup> Joint Commission on Accreditation of Healthcare Organizations. Accreditation manual for hospitals. Vol 1- standards. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations 1992; 21-2.

<sup>18</sup> US Preventive Services Task Force. *Guide to Clinical Preventive Services* (3<sup>rd</sup> Edition). Baltimore, MD: Williams & Wilkins, forthcoming publication.

<sup>19</sup> Canadian Task Force on the Periodic Health Examination. Assessing the clinical effectiveness of preventive maneuvers. *Journal of Clinical Epidemiology* 1990; 43: 891-905.

<sup>20</sup> UK National Screening Committee The criteria for appraising the viability, effectiveness, & appropriateness of a screening programme. Available at: <http://www.nsc.nhs.uk/pdfs/criteria.pdf> <http://www.nhs.uk/criteria.pdf> Accessed May 18, 2011.

<sup>21</sup> US Preventive Services Task Force. Screening for Family and Intimate Partner Violence: Recommendation Statement. *Ann Intern Med* 2004; 140: 382-386.

<sup>22</sup> Ramsay, J, Richardson, J, Carter, Y, Davidson, LL., Feder, G. Should health professionals screen women for domestic violence? Systematic review. *BMJ* 2002; 325: 314-318.

<sup>23</sup> Wathen, C.N. & MacMillan, H.L. Interventions for Violence Against Women. Scientific Review. *JAMA* 2003; 289: 589-600.

Whether intervention offered to patients during the asymptomatic phase is utilized by victims, and is more efficient and effective in improving health 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 and social support among victims. However, 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.<sup>25</sup> Women also report feeling disappointed in their health care providers' behavior, often finding the provider uninterested, uncaring, or uncomfortable.<sup>26-27</sup>

Current recommendations promote health care provider screening and referral. However, even if there were evidence of the benefits of screening for IPV, having health care providers screen and refer women would be difficult to implement, given the time constraints of the primary health care provider-patient encounter.<sup>28</sup> Computerized health screening is an attractive alternative in that it is relatively low cost, staff free, and flexible; can be programmed to screen opportunistically; easy to use; and more easily introduced into the patient care flow.<sup>29</sup> 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<sup>30,31,32,33,34</sup>, including IPV<sup>35-36</sup>, is acceptable to

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<sup>24</sup> Babcock, IC, Wyer, PC, Gerson, LW. Preventive care in the emergency department, Part II: Clinical preventive services—an emergency medicine evidence-based review. Society for Academic Medicine Public Health and Education Task Force Preventive Services Work Group. *Acad Emerg Med* 2000; 7: 1421-3.

<sup>25</sup> Chang, JC, Decker, M, Morocco, KE, Martin, SL, Petersen, R, Frasier, P. What happens when health care providers ask about intimate partner violence? A description of the consequences from the perspective of female survivors. *JAMWA* in press.

<sup>26</sup> Hamberger, LK, Ambuel, B, Marbella, A, Donze, J. Physician interaction with battered women: The woman's perspective. *Arch Fam Med* 1998; 7: 575-582.

<sup>27</sup> Gerbert, B, Johnston, K, Caspers, N, et al. Experiences of battered women in health care settings: A Qualitative Study. *Women Health* 1996; 24: 1-17.

<sup>28</sup> Gilchrist, VJ, Stange, KC, Flocke, SA, McCord, G, & Bourghet C. A comparison of the National Ambulatory Medical Survey (NAMCS) Measurement Approach with Direct Observation of Outpatient Visits. *Medical Care* 2004; 42: 276-280.

<sup>29</sup> McNutt, LA, Waltermauer, E, McCauley, J, Campbell, J, Ford, DE. Rationale for and Development of Computerized Intimate Partner Violence Screen for Primary Care. *Family Violence Prevention and Health Practice* 2005; 1-14.

<sup>30</sup> Gerbert, B, Bronstone, A, Pantilat, S, McPhee, S, Allerton, M, Moe, J. When asked, patients tell: disclosure of sensitive health-risk behaviors. *Medical Care* 1999; 37: 104-111.

<sup>31</sup> Des Jarlais, DC, Paone, D, Milliken, J, Audio-computer interviewing to measure risk behavior for HIV among injecting drug users: a quasi-randomised trial. *Lancet* 1999; 353: 1657-1661.

<sup>32</sup> Gribble, JN, Miller, HG, Cooley, PC, Catania, JS, Pollack, L, Turner, CF. The impact of T-CASI interviewing on reported drug use among men who have sex with men. *Substance Use and Misuse* 2000; 35: 869-890.

<sup>33</sup> Turner, CF, Ku, L, Rogers, SM, Lindberg, LD, Pleck, JH, Sonenstein, FL. Adolescent sexual behavior, drug use and violence: increased reporting with computer survey technology. *Science* 1998; 280: 867-873.

patients and health care providers, and increases solicitation and recall of health advice.<sup>37</sup> Thus, in this study, we will test the effectiveness of computerized routine screening.

Finally, there is some debate about whether screening is actually needed to provide information about available IPV resources.<sup>38</sup> There is also evidence that many abused women do not disclose IPV to their health care provider when they are screened.<sup>39</sup> Routinely providing **all** women with information on available IPV resources might facilitate access to these services for women who are not ready or willing to disclose to their health care provider. The effectiveness of this alternative, which we have named “universal education”, will also be tested in this study.

### Objective

The objectives of this study are to establish the cost and effectiveness of routine screening for IPV and referral to IPV services of asymptomatic women compared to universal education or no intervention on disability, quality of life, utilization of health care services and IPV services, and exposure to IPV, and to identify other potential side effects (adverse and beneficial) of these interventions.

### Intended/potential use of study findings

The findings from this study will guide CDC in formulating its recommendations regarding routine screening, 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.

## *METHODS*

### Overall design

We propose conducting a randomized controlled trial with three arms. In the first arm, participants will be screened, and only if disclosing IPV, will receive information on available resources in the community. In the other two arms, participants will not be screened, but one group will receive information on available IPV resources in the

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<sup>34</sup> Newman, JC, Des Jarlais, DC, Turner, CF, Gribble, J, Cooley, P, Paone, D. The Differential Effects of Face-to-Face and Computer Interview Modes. *American Journal of Public Health* 2002; 92: 294-297.

<sup>35</sup> Rhodes KV, Lauderdale DS, He T, Howes DS, Levinson W. "Between me and the computer": Increased detection of intimate partner violence using a computer questionnaire. *Ann Emerg Med* 2002; 40: 476-484.

<sup>36</sup> Renker PR & Tonkin P. Women’s Views of Prenatal Violence Screening: Acceptability and Confidentiality Issues. *Obstetrics and Gynecology* 2006;107: 348-354.

<sup>37</sup> Rhodes, KV. The Promise and Problems of Using Information Technology to Achieve Routine Screening for Intimate Partner Violence. *Family Violence Prevention and Health Practice* 2005; (3): 1-14.

<sup>38</sup> Runyan, D. (2002) Personal communication.

<sup>39</sup> Renker, PR & Tonkin, P. women’s Views of Prenatal Violence Screening. *Obst Gynec* 2006; 107: 348-354.

community and the other will not receive this information. All three groups will be assessed with a self-report measure for disability, and quality of life at baseline and at a 12-month follow-up. Health records will be used to assess for utilization of health care in the past year at baseline and at one- and three-year follow-ups. Two-year follow-up of mortality data will also be collected. Exposure to IPV and utilization of IPV services or social support will be assessed only at the one-year follow-up.

### Location

This study will be conducted at the following facilities that are within the Cook County Bureau of Health Services: the Fantus Health Center, the CORE center, Ambulatory Health Care Network, and the Rush- Presbyterian-St. Lukes Medical Center. The Bureau, which includes the John Stroger Jr. Hospital of Cook County (formerly Cook County Hospital) and its 31 community clinics, including the Cermak medical facility at the Cook County Jail and two community hospitals (Oak Forest and Provident), annually provides 24,644 hospital admissions, 120,000 emergency department visits and over 600,000 outpatient visits to people who are uninsured and underinsured.

1) The Fantus Health Center, adjacent to Stroger Hospital, is the flagship clinic of the Cook County Bureau of Health Services ambulatory facilities. It provides comprehensive general medicine, obstetrical, gynecologic and family planning services through several mechanisms. Obstetrical services are provided five days a week through both resident and midwifery clinics. Gynecological and family planning services are provided five days a week by resident, physician assistant, and attending clinics, in addition to family planning services which are also provided separately by nurse practitioners through a Title X grant. The family planning grant is run under the auspices of the Department of Obstetrics and Gynecology; hence staff from the department provides services in both clinics. The average number of visits per day to Obstetrics & Gynecology is 90 while Family planning averages 25 visits per day. The General Medical Clinic (GMC) is a large adult ambulatory care clinic that provides 30,000 continuity ambulatory care visits a year and about 240 visits a day. The majority of patients are African American (80 %), women (65%) and have an average age of 61.5 years.

2) CORE Center: Participants will also be recruited from the Ruth M. Rothstein CORE Center, a state of the art clinical facility founded by the Cook County Bureau of Health Services. The CORE Center is a one-stop approach to treatment and prevention for sexually transmitted diseases that serves as a national model for outpatient services. Women at the CORE Center are seen in dedicated clinics that operate 4 half days a week and offer supportive services such as child-care and case management. Approximately 85-100 women are seen weekly for HIV related primary or obstetrics & gynecologic care and about 30-40 women are seen weekly in the CORE Center Screening clinic which provides walk-in services for sexually transmitted infection (STI) related complaints. While routine IPV screening is not currently done, the CORE Center recognizes its importance and in conjunction with HCIP is certifying a registered nurse to provide intervention services in 2009. We expect to enroll 10-15% of the study participants from this clinic to ensure representation of this high-risk population.

3) The Ambulatory Health Care Network of Cook County provides primary care services at 10 community locations – six in Chicago and 4 in adjacent neighborhoods within Cook County. We will select two sites based on their volume of adult women patients as well as their interest in serving as a study site. To be eligible, the clinics will need to provide primary care to over 5,000 adult women annually (80% meet this volume criteria) and have reliable internet access to meet the aCASI needs of the study. The IPV study will enroll 5-10% of the study sample from 1-2 of the clinics located in Chicago.

4) Rush Medical Center, designed to serve approximately 3 million people, is a nonprofit academic medical center comprised of Rush University, a 613 bed hospital in Chicago, medical centers in Oak Park, Aurora and Skokie, Illinois and the Rush Health Associates, a provider network with 700 physicians on staff at various locations. Sites from the Medical Center and Rush Health Associates that provide women’s health care services will be participating in the project. The initial Rush clinical site will be Rush Associates in Women’s Health at 1645 West Jackson street. In that practice 8 attending physicians and multiple resident physicians provide outpatient obstetrical and gynecologic services. A secondary potential site is the Women’s Health Consultants practice located in the professional building on the Medical Center campus which also has 8 attending physicians of various subspecialties providing patient service. We anticipate that 15-25% of the study population will be recruited from these locations.

<u>Tentative Time Table: month starting after completion of pilot study</u>	
<u>Month</u>	<u>Project Activity</u>
1-3	Revise measures/procedures based on pilot test Submit amendments to IRB & modifications to OMB
4-9	Enroll and interview participants
10	Extract demographics and health care utilization from Electronic Database
16-21	One-year follow-up interviews
22-24	Clean and merge databases; Begin manuscript writing
24-27	Data analysis
28-36	Finish preparing manuscripts
46-48	Develop security authorization documentation and plan for protection of identifiable information
49-50	Submit amendment to IRB
51-52	Pilot query to assess completeness of ICD-9 codes in electronic medical records
53-56	Extract 3-year health care utilization from Electronic Medical Records
57-60	Extract and code 2-year mortality from Vital Statistics

61-62	Mortality data entry, clean and merge health care utilization data
63-64	Data analysis
65-70	Preparation of reports

### Study population

All women at least 18 years of age seeking services at any of the study sites are eligible for inclusion. The following table provides our exclusion criteria and rationale:

<b>Exclusion Criteria</b>	<b>Rationale</b>
Non-English or Spanish speaking	Audio programming and video clips in multiple languages is cost-prohibitive
Women accompanied by a child >3 years of age who don't have adequate provision for child care	Older children may compromise the privacy of the kiosk and for security reasons, they should be with their caretaker
Visually- or hearing-impaired women	They will be unable to use either the A-CASI or the touch-screen monitor
Women who are accompanied by their partner and the two can't safely be separated	Patient privacy is essential for the safety of participants
Women who do not have access to a telephone	Unable to complete study task – 1 year CATI follow-up
Women who will not give contact information of at least 2 family members or friends	Unable to meet expected CATI 1-year follow-up without additional contact options
Severe Mental impairment	Unable to give Informed Consent and complete study tasks

### *Sample size and statistical power*

The sample size needed to detect a standardized effect size of .4 (considered a moderate effect size; Cohen, 1998) in QOL and mental health score means at a significance level of .05, power of 80%, factoring in a 30% lost-to-follow-up rate<sup>40</sup>, is 110 abused women in each arm. Based on the average obtained from four prevalence studies, we might expect that about 13% of women in primary or ambulatory care clinics report being abused by a partner in the past year.<sup>41,42,43,44</sup> Thus, the minimum sample size needed in each group is

<sup>40</sup> Based on observations from Coker, A, Smith, PH, Flerx, VC, et al. Domestic Violence Services in Rural Health Care Clinics ongoing screening and intervention trial.

<sup>41</sup> Bauer H, Rodriguez MA, Perez-Stable EJ. Prevalence and determinants of intimate partner abuse among public hospital primary care patients. *J Gen Intern Med* 2000;15: 811-817.

<sup>42</sup> Richardson J, Coid J, Petrukevitch A, et al. Identifying domestic violence: cross-sectional study in primary care. *BMJ* 2002; 324:271-277.

equal to 847. Mean scores on these continuous variables will be estimated based on the pilot study and the sample size will be adjusted accordingly.

Given our setting, and the time needed to successfully enroll each participant, our enrollment goal minimum will be 300 interviews completed per week. To achieve this goal we intend to enroll from multiple clinics every day. We anticipate our final sample will include 30-45% of participants enrolled from the Fantus OB/GYN clinics, 5-10 % from other Fantus Primary care clinics such as the General Medical Clinic (GMC), 10-15% from CORE, 5-10% from other ambulatory health care network clinics and finally 15-20% from Rush Medical Center clinics.

*Identification of potential study participant:* Nursing staff will distribute an informational flyer (please see appendix) with the patient's registration label to patients after weight and blood pressure is assessed. Patients may show their interest in the study by depositing their flyer in a bin labeled "Women's Health and Computer Study" on the reception desk. These patients will be contacted by a Research Assistant (RA). Women who are not interested will be directed to hand it to provider or other staff who will then destroy it. In addition, RAs will approach other potential participants during their wait to be seen by the providers to determine their interest and then if appropriate their eligibility. Regardless of method of recruitment, all potential participants will undergo the enrollment and consent process described below.

*Enrollment and consent:* Women called by the RA in the waiting room will be screened for eligibility (see sample script for eligibility in appendix) and, if eligible, invited to participate in this study, including the follow-up telephone interview one year later. The RA will offer women a copy of the consent form (please see Appendix) and will also read it aloud to her. Those consenting will be asked to go to a computer kiosk with the RA and respond to the questionnaire. Women will be compensated with \$20 at baseline and a \$15 gift certificate at the one-year follow-up for their time.

## Variables and Measures

### Independent variable

*Screening and referral strategies.* Participants will be randomly assigned to one of the following three arms after they are determined to be eligible and Informed Consent procedures are complete:

Arm 1: Audio-computer-assisted structured interview (A-CASI) baseline survey + IPV screen, referral if positive;

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<sup>43</sup> McCauley J, Kern DE, Kolodner K, et al. The "battering syndrome": prevalence and clinical characteristics of domestic violence in primary care internal medicine practices. *Ann Intern Med* 1995; 123: 737-746.

<sup>44</sup> Gin NE, Ruker L, Frayne S, et al. Prevalence of domestic violence among patients in three ambulatory care internal medicine clinics. *J Gen Intern Med* 1991; 6: 317-322.

Arm 2: A-CASI baseline survey, no IPV screen, universal education on IPV resources;

Arm 3: A-CASI baseline survey, no IPV screen, no referral information.

*Random assignment of study participant.* The CASI program will randomly assign the participant to one of 3 study arms as described in the Study Design above. We will implement a simple randomization technique. After obtaining informed consent, the RA will lead the participant to the kiosk, and activate the CASI program. After the RA enters the study ID number into the CASI program, the computer screen will indicate with a message/symbol the assigned arm or study group.

*IPV screen.* The Partner Violence Screen (PVS) will be used to assess the presence of current IPV (past year) and women's perception of being 'safe' from IPV<sup>45</sup> for participants in arm 1. This 3 item screening tool has been used in Emergency Room settings where it was validated using the much longer IPV research instruments — Index of Spouse Abuse (ISA) and the Conflict Tactics Scale (CTS) as criterion. The sensitivity of PVS was .65 (compared to ISA) and .71 (compared to CTS); specificity for the PVS was .80 (ISA) and .84 (CTS). The three items of the PVS are:

1. Have you been hit, kicked, punched or otherwise hurt by someone with the past year?  
If yes, Follow-up question – by whom?
2. Do you feel safe in your current relationship?
3. Is there a partner from a previous relationship who is making you feel unsafe now?

A positive screen is a 'yes' response to Question 1 (with indication of perpetrator as fitting intimate partner definition) or a 'yes' response to Question 3, or a 'no' response to Question 2.

*Referral information on IPV services.* Women screening positive for IPV in arm 1 as well as all women in arm 2 will receive information on local IPV services. The printout (see appendix) will refer women to the Cook County Bureau of Health Services IPV program (Hospital Crisis Intervention Program or HCIP) as well as other off-site Chicago referral options. The HCIP, located on the first floor of Fantus, is the domestic violence training and advocacy program at Cook County Hospital. HCIP is a collaboration between the Chicago Abused Women Coalition (CAWC) and the Cook County Bureau of Health Services. A forerunner program located in an inner-city public hospital, HCIP has been hailed as a national model for hospital-based domestic violence services and training. HCIP provides direct services to victims of abuse that include crisis intervention, safety assessment and planning, individual counseling, information about their legal rights, court and systems advocacy, access to emergency shelter, financial assistance and referrals to other needed resources.

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<sup>45</sup> Feldhaus, KM, Koziol-McLain, J, Amsbury, HL, Norton, IM. Accuracy of 3 Brief Screening Questions for Detecting Partner Violence in the Emergency Department. JAMA 1997; 277: 1357-1361.

Each year, HCIP responds to approximately 700 referrals from clinicians and provides over 900 hours of direct services to over 400 clients. HCIP's advocates are currently available Monday through Friday, 8:00 am to 9:00 pm. Services are provided in English and Spanish by a multicultural staff that has received extensive training in domestic violence advocacy, racism and oppression and available resources. HCIP's staff is comprised of four full-time domestic violence advocates, one full-time direct services coordinator and a full-time co-director, all of whom are employed by the Chicago Abused Women Coalition (CAWC), the oldest domestic violence agency in Chicago.

In order to avoid identifying women who screen positive for IPV to others in the clinic, women screening *negative* in arm 1 and all women in arm 3 will also receive a computer printout. This printout will contain a list of local health resources for women (please see appendix).

#### *Outcome variables*

a. *Quality of Life (QOL)*: will be measured with the SF-12<sup>46</sup> at both baseline and at the one-year follow-up (section A of baseline and follow-up). This 12-item tool was shortened from the SF-36 to maximize efficiency and best reflect the physical and mental health subscale scores. This 12-item instrument has demonstrated ability to detect change in health status over periods of one year, including recovery from depression as well as physical health. The administration time is approximately 2 minutes. The SF-12 includes 12 questions that measure overall health (1 item), physical functioning (2 items), role limitations due to physical health problems (4 items), bodily pain (1 item), energy/fatigue (1 item), social functioning (1 item), and psychological distress and well being (2 items; see questionnaire, section). This measure has shown acceptable reliability and validity<sup>32</sup>, and summary scores of the SF-12 can be used to derive a utility value for the health state reported through an established algorithm. This transformation of the SF12 score represents what the general population believes is the quality of life associated with each woman's health state and allows comparisons with other conditions similarly standardized. This tool has been successfully and extensively used to assess QOL in clinical trials, and is amenable to CASI format.

b. *Mortality*: Two of five women murdered in the US are murdered by an intimate partner resulting in over 1,100 deaths among women yearly.<sup>47</sup> As such, the potential impact on mortality of the two interventions proposed in this trial is of interest. We will obtain two-year mortality data from the Illinois Department of Health's Division of Vital Records.

c. *Disability* will be assessed at both baseline and at the one-year follow-up utilizing the same time period. We propose two items to assess disability or inability to perform usual

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<sup>46</sup> Ware JE, Kosinski M, Keller SD. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;34(3):220-233.

<sup>47</sup> Cooper A, Smith, EL. *Homicide Trends in the United States, 1980-2008*. US Department of Justice, Bureau of Justice Statistics, 2011 (see spread spreadsheets for total number of deaths) Accessed January 25, 2013 at: <http://bjs.ojp.usdoj.gov/index.cfm?ty=pbdetail&iid=2221>.

tasks over the past year (see questionnaires, section B at baseline and section C in follow-up). These two items assess days missed from work outside the home and days unable to perform usual household tasks and were used successfully in the WorldSAFE IPV study.<sup>48</sup>

d. *Utilization of health care services.* The frequency and type of health service visits (i.e., hospitalizations, emergency room visits, and out-patient visits) will be assessed for the 12 months previous to the baseline interview date and during the three years following enrollment and random assignment utilizing the Electronic Medical Record Database. Diagnoses based on ICD-9 codes will also be extracted for the three years following enrollment and random assignment to determine potential impact of the two interventions on morbidity presumed to be caused by IPV. We will review full medical records for a subsample of the first 15 participants recruited at each clinic to establish potential missing diagnoses not documented in the electronic records. All medical care encounters with any of the Bureau's three hospitals and 31 clinics of the Cook County Bureau of Health Services are stored in this electronic medical record database. This system captures >90% of all in- and out-patient service use in public system of Cook County. Participants will also be asked in the baseline and one-year follow-up surveys about hospitalizations and ED visits in the past year *outside* of the Bureau's network (see questions in section C).

e. *Exposure to IPV:* At one-year follow-up, all women will be asked about IPV exposure during their lifetime and, if answering affirmatively to any of the IPV questions, if they are currently with this partner or how long ago they separated from the most recent partner who was violent (please see section E of follow-up measures). These two questions will allow us to determine exposure to IPV in the past year and during the year before the intervention. To assess exposure to IPV, we will use 10 of the items measuring simple and aggravated assault (threaten and use a gun and threaten and use a knife or other weapon have each been collapsed into 2 items), one of the items measuring sexual assault, and the seven items measuring control utilized in the National Violence Against Women Survey (NVAWS).<sup>2</sup> Factor analysis of the NVAWS data collected with the seven control items suggested that these items measured one construct reliably (Cronbach  $\alpha=.70$ ).<sup>49</sup> These nonviolent control items will allow us to distinguish between situational couple violence (resulting when conflict escalates into mutually violent interactions) and so called "intimate terrorism" (male-to-female aggression motivated by the intent to control).<sup>50</sup> Because these two types of IPV are hypothesized to have a different natural history and outcomes, the impact of any intervention might also differ. Once the interview has terminated, all respondents will be given the HCIP crisis line number and the 1-800 national IPV hotline in case they would like more information on IPV or would like assistance for themselves or someone they know.

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<sup>48</sup> Sadowski, LS, Hunter, WM, Bangdiwala, SI, Muñoz, SR. The world studies of abuse in the family environment (WorldSAFE): a model of multi-national study of family violence. *Injury Control and Safety Promotion* 2004; 11: 81-90.

<sup>49</sup> Johnson, MP & Leone, JM. The Differential Effects of Intimate Terrorism and Situational Couple Violence. *Journal of Family Issues* 2005; 26: 322-349.

<sup>50</sup> Johnson, MP & Ferraro, KJ. Research on domestic violence in the 1990s: Making distinctions. *Journal of Marriage and Family* 2000; 62:948-963.

f. *direct costs of intervention*: the additional costs incurred in arms 1 and 2 will be estimated based on start-up costs (computers, printers, acquisition and adaptation of existing programs for computer-assisted health screening, patient kiosks for privacy) and ongoing costs (space utilized, technical assistance required, participant time spent in IPV screening questions, printouts, and services utilized by the study participants).

g. *potential side effects of intervention*.

1) Beneficial effects (see section D of follow-up questionnaire):

- *Knowledge of the prevalence of IPV*: Answer to the question: “If there were 10 women sitting in a room, how many of these women would you guess have **ever** been physically, verbally, emotionally, or sexually threatened or harmed by an intimate partner.” Women responding between 2-3 will be categorized as having knowledge of the prevalence; those responding below 2 will be categorized as underestimating the prevalence and those responding above 3 will be categorized as overestimating the prevalence;
- *Knowledge of seriousness of IPV*: perceived likelihood of physical and mental health problems among victims of IPV compared to non-victims. It will be considered beneficial if women respond that victims are more likely to have problems with their physical and mental health;
- *Knowledge of available services for victims of IPV*: Reporting at least one local service in response to the question “Where can a woman who is being abused by an intimate partner get help in this community?”;
- *Attribution of responsibility for violence*: Agreement or disagreement with the statement “Women usually get hit by their partners because of something they (the women) did”. It will be considered a benefit if women attribute responsibility to the perpetrator.
- *Perceived availability of services for IPV*: Agreement or disagreement with the statement “Women who are abused by their partners can get help if they need it”.

2) Adverse effects: Participants will be asked at the one-year follow-up if they experienced any problems as a result of their responding to our questions or receiving information as a participant in the study. (Please see section F of follow-up questionnaire, #2 and 6).

*Mediating variables*

*Contact with IPV resources*: Women will first be asked if they remember receiving a list of names of agencies that provided help for women exposed to IPV on the date of their recruitment visit. If they do, they will be asked if they shared the list or contacted any of the agencies. They will also be asked if they had had any contact with this or any other IPV service before joining the study. (See Section F, #3-7 for these questions).

*Disclosure*: Women answering affirmatively to any of the IPV questions (variable e), will be asked if they have discussed this (or these) experiences with anybody, and if affirmative, if this occurred before joining the study (See section E, #21).

### *Potential confounders*

- a) *Demographics*: age, race/ethnicity, and insurance status will be based on information in the Cook County Bureau of Health Services Electronic Medical Record Database and educational level will be assessed during the follow-up interview (section G).
- b) *Symptomatic/Asymptomatic*: because evidence is needed that early treatment (during the asymptomatic period) produces better results than waiting for the appearance of symptoms and a diagnosis, we will establish the presence of signs or symptoms at baseline of conditions that have been associated with IPV<sup>51-52</sup> (see section C of baseline measure) and explore potential effects in the asymptomatic group.
- c) *Contamination*: exposure to other health care providers who might screen or offer IPV resources will be assessed with the question “In the past year, has a doctor, nurse, or other health care provider ever asked you if you were afraid of a current or former intimate partner or if a current or former intimate partner had hurt or threatened you?” in the follow-up interview.
- d) *Baseline* mental health status, disability, quality of life, and utilization of health care will be measured with the same measures proposed for outcomes.

### Data collection

Baseline data collection will take place at several separate locations within the Fantus Clinic as well as the CORE center, two sites within the Ambulatory Health Care Network, and the Rush- Presbyterian-St. Lukes Medical Center until the study sample is enrolled. The identification of potential participants and sampling procedure have been described previously (p.8). Women attending each site and called by the RA in the waiting room will be screened for eligibility (see sample script for eligibility in appendix) and, if eligible, invited to participate in this study, including the follow-up telephone interview one year later. The RA will offer women a copy of the consent form (please see Appendix) and will also read it aloud to her. Those consenting will be asked to go to a computer kiosk or private office with the RA and respond to the questionnaire on a touch screen computer.

All baseline information except for age, race/ethnicity, health insurance status, and utilization of health care outside the Cook County Bureau of Health services will be based on self-report and collected at the time of recruitment using an audio-computer-assisted structured interview (A-CASI). (See questionnaire in appendix). The A-CASI program will include the text of the question wording, response category wording, and the programming of the skip patterns, and range checks and other on-line consistency checks and procedures during the interview

After recruiting eligible patients and completing informed consent procedures, the RA will activate the A-CASI program and assign the participant a unique identification

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<sup>51</sup> Campbell J, Jones AS, Dienemann J, et al. Intimate partner violence and physical health consequences. *Arch Intern Med* 2002; 162:1157-1163.

<sup>52</sup> Coker AL, Smith PH, Bethea L, et al. Physical health consequences of physical and psychological intimate partner violence. *Arch Fam Med* 2000;9:451-457.

number. The participant will be randomized to one of the study arms using a computer-generated random number generator. Randomization will be stratified by clinic and performed in permuted blocks to balance the number of participants for the study arms. If, for whatever reason, the participant does not complete the entire questionnaire, by using their unique study number, they will be able to restart the interview at their last completed question. Participants may skip questions if they choose. If they are interrupted and do not complete the questionnaire, they may continue where they left off. The RA who recruited the participant will have their unique study number and will key it into the computer when the participant is ready to resume the interview. If necessary, the laptop and printer are portable and can be moved from the office/kiosk to the health care provider's exam room and completed while the patient waits for her provider. Research field staff will be available to assist women, if needed. It is estimated that, on average, the baseline questionnaire will take about 15 minutes to complete.

*Wrap-up session.* RAs will meet with the participant they enrolled after she has completed her A-CASI. During the wrap up, the RA will try to establish some rapport and negotiate telephone appointment dates/times for the one-year follow-up interview. She will ask participants to provide a preferred contact number, two alternate contact numbers, and the names and contact numbers of two people with whom she maintains regular contact. During this negotiation, the RAs will emphasize the woman's convenience and safety. Times not to call will be recorded in RAs' log, as well as notes including agreed to safety signs (i.e., a safe word, identified by the woman to indicate if the woman is not able to safely answer the question). Additionally, during the wrap up, the RA will negotiate a safe message to leave on the participants' voice mail or answering machine. The RAs will give each woman a card with the toll-free number and RA's name noting the preferred time and two alternate times for the follow-up interview. The participant will be encouraged to inform the project of changes in her contact information by calling this 24-hour toll-free number. At the end of the wrap-up, the RA will discretely distribute the \$10 compensation (unsealed envelope) and will note the time the woman has completed the study activities (and clinic visit).

RAs will extract and input into participants' study files demographics (age, race/ethnicity, pregnancy and health insurance status) and information on participants' health care utilization in the past year (from baseline interview) from the Cook County Bureau of Health Services Electronic Medical Record Database.

*One-year follow-up interview.* Participants will be contacted at least once by phone and possibly one or two more times by mail to remind them of the phone interview and verify contact information and plans for the next few months, and to review strategies agreed on at baseline for contact and ensure that these methods remain safe and appropriate. Eleven months after completion of the baseline interview, efforts will begin for the follow-up of participants and will continue up to 4 weeks after the one-year date. The same RA that enrolled the participant will be responsible for follow-up of that participant. RAs will schedule calls based on days and times participants' reported preferring at baseline. All information, except selected demographics and health care utilization, will be collected at the one-year follow-up using a computer-assisted telephone interview (CATI). The RA

will open the CATI application and enter the study identifier, log the date and time of contact. For patients who cannot be contacted on the initial attempt, the interviewer will attempt a follow-up call to each of the numbers the participant provided up to 4 times on 3 consecutive days during times specifically negotiated with the women at enrollment, including calls during evening hours. After successful or failed follow-up contact, the patient will be removed from the report and considered as a failed contact. For partially completed or refused follow-up interviews the participant will be asked about the reason for termination of the interview (e.g., safety concerns or time pressures). The CATI program will create an automatic record of all dialings, track the outcome of each contact/interviewing attempt, and document reasons for refusal and the place of termination.

Once contact with participants is established for the follow-up, the interviewer will either proceed with the interview or schedule the interview at a time convenient to the respondent. For patients who are unable to complete the interview, but who request the opportunity to resume the interview at a later date, work will be saved and the interviewer and interviewee will have the option of resuming the interview without repeating questions. This interview will take approximately 20 minutes to complete. Participants will receive a \$15 gift certificate in the mail to compensate them for their time and effort.

CATI follow up interviews will be conducted in the Collaborative Research Unit at Stroger-CATI office (Room 1608) following CRU protocol for attempts, response to disconnect, script for call answered by other, etc.) The CATI program will include the text of the question wording, response category wording, and the programming of the skip patterns, and range checks and other on-line consistency checks and procedures during the interview as well as a system to help eliminate the problem of key entry error as a result of accidentally hitting the wrong key. For quality control, these activities will be supervised or reviewed by the study coordinator.

To establish overall health care utilization and utilization by conditions presumptively related to IPV, we will extract data from Cook County Bureau of Health Services' electronic medical records to establish the number and diagnoses using ICD-9 for ambulatory health care visits, emergency department visits, and hospitalizations at any County health care site occurring within a three year period from time of enrollment among the RCT of IPV Screening participants. A pilot query will be conducted on the first 15 participants enrolled in the trial at each clinic to compare diagnoses in the electronic medical record with a full medical record review. This will establish the magnitude and type of missing diagnoses in the electronic medical record and will attempt to account for the limited number of diagnoses that can be included in the electronic medical records. This pilot query will also help identify the set of variables to extract from the electronic medical record database in order to establish the number and diagnoses for ambulatory health care visits (excluding laboratory and radiology visits), emergency department visits, and hospitalizations at any County health care site. Data extracted from the electronic medical record database will be stored on a zip drive in an encrypted format. This database will be in an Access format and loaded onto a single

stand alone PC and then de-identified (unique study ID #s only). Access to that PC will be limited and physical protections will be put in place.

To establish overall mortality rates by study group and mortality rates by specific causes presumed to be consequences of IPV during the two years following enrollment and random assignment, we will submit participants' name and date of birth to the Illinois Department of Health's Division of Vital Records. They will search their records to determine if a death has occurred and, if a death has occurred, they will provide a copy of the death certificate from which the immediate and underlying causes and manner of death will be abstracted. Death certificates will be kept in a locked file cabinet in a locked study office and access will be limited to 2 investigators and the project coordinator. All certificates will be destroyed once data are abstracted and analyses completed.

*Training and supervision of study personnel.* All field staff (RAs) will have received 8-12 hours of training by the Research Team. The content of training will include: eligibility determination, recruitment, informed consent, enrollment, A-CASI operations, and CATI follow-up. In addition, interviewers will also receive information on IPV and its consequences and will receive instructions on what to do if a respondent reports exposure to IPV, if an incident occurs or a respondent asks for help during the CATI. Interviewers/RAs will not know at baseline if a participant is exposed to IPV unless the participant spontaneously reports this to her. Should this occur, interviewers will have been made aware during the training of three main principles in the management of persons who acknowledge partner violence or who ask for assistance around partner violence: (1) The safety of the individual and children; (2) Respect for the autonomy of the adult patient; and (3) Hold the perpetrator - not the survivor- responsible for the abuse. Based on these principles, interviewers will be instructed to remain calm and ask the participant if she would like to do something about the situation. If she chooses to do nothing about it at the moment, the interviewer will emphasize that services are free of charge and confidential, and provide the HCIP number as well as the interviewer's number, should she change her mind. If the respondent says she would like to do something, the interviewer will ask about immediate safety concerns and whether the abuser is on the medical campus. If the abuser is on the campus then the interviewer will ask whether the participant wants the police to intervene or not. If the participant feels safe at the moment, the interviewer will ask if she would like counseling, in which case she will offer to call the HCIP or will provide the HCIP's number so that the participant can make the call herself. Staff will be instructed to keep in mind that some women who answer yes may prefer to make a call themselves to a help line or the police without any assistance. In that case, staff will be instructed to provide a safe, confidential room for them to make a call at the medical center. If the participant does not want counseling at that time, staff will let her know that if she changes her mind, she can always contact a counselor at a later time and that we will tell her how to do so.

Interviewers will be instructed to respond empathetically but nonjudgementally to participants who report exposure to IPV during the follow-up interview (e.g., "I see", "That's helpful for us to know"). In Q21 of Section F of the follow-up questionnaire, we ask if she has talked to anybody about these experiences and if she says "no", we ask if

she would like to talk to someone. If she does, the interviewer will say “at the end of our interview I will give you a number you can call.” If she does not, the interviewer will say “just in case you change your mind, at the end of our interview, I will give you a number you can call.”

Telephone interviewing techniques will be modeled utilizing the study questionnaire and practiced by trainees through role-play. Trainees will be observed and given feedback during simulations of the interview until they are able to perform each skill to the PI’s satisfaction.

*Pilot study.* Measures, methods, and procedures will be tested in a pilot study (presented in a separate protocol) to establish their feasibility and acceptability. The pilot study will compare health care provider screening, referral, and support to A-CASI screening and referral with different variations (i.e., with and without provider support or video clip support). The pilot will also provide estimates of our main outcome measures and the concordance between the two data collection methods proposed. Adjustments in screening and referral strategy, questionnaire items, sample size, or procedures will be made based on the results of this pilot study. Resulting modifications will be submitted to the IRB as an amendment.

*Data entry, cleaning, and management.* Both the A-CASI and CATI programs will result in automatic data entry for most of our variables through the user interface and will automatically detect errors as a result of accidentally hitting the wrong key requiring the respondent/interviewer to confirm the entry. We anticipate that data entry will be directly into the SQL server database on the servers maintained by CRU and housed by the Hospital Information System Department. If network connectivity is unsuccessful from some of the laptop locations, data entry will be automated into a Microsoft Access database, and data uploaded into the SQL server database.

The terminal database will be Microsoft SQL server, which provides enhanced security protection beyond Access databases. The levels of protection include the firewall for the Department of Medicine, password-protected intranet access, and also password protection for access to the SQL server database. Database access will be restricted to members of the investigative team mentioned in this proposal. In addition, ad hoc access may be granted for research personnel who are added to the project. Locally stored Access databases will be erased after verifying the data were successfully uploaded to the SQL server. These data will be maintained on the SQL server database until publications are completed.

Data extracted from the electronic medical record database for the three-year follow-up of morbidity will be stored on a zip drive in an encrypted format. This database will be in an Access format and loaded onto a single stand-alone PC and then de-identified (unique study ID #s only). Access to that PC will be limited and physical protections will be put in place. Number and ICD-9 codes of hospitalizations and ambulatory care visits occurring within the three-year follow-up window will be abstracted and entered into the SQL server database and then merged with the study database.

Death certificates obtained for the two-year follow-up will be kept in a locked file cabinet in a locked study office and access will be limited to 2 investigators and the project coordinator. Immediate and underlying causes and manner of death will be extracted and added to the study database. All certificates will be destroyed once data are abstracted and analyses completed.

#### Data analysis plan

Data will be extracted and analyzed with SPSS and STATA directly from the CASI or CATI systems. Two-year mortality and three-year morbidity data will be added to the study database once collected.

*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 between groups as to confounders (sociodemographics, baseline QOL, disability, and health care utilization).

*Impact of intervention:* If there are no significant differences between groups on the selected confounders, a one-way analysis of variance will be conducted to establish differences in means among the two intervention and control groups and percentages will be used to establish differences between categorical variables. If there are differences in confounders between groups, multivariate techniques will be used to control for these differences and establish potential effects of intervention.

#### *DISSEMINATION*

Findings from this study will be disseminated through publications in professional journals.

#### PROTECTION OF HUMAN SUBJECTS- ADDITIONAL INFORMATION

##### *Potential risks and methods to minimize risks*

We expect the occurrence of adverse effects as a result of this trial to be minimal and comparable to those encountered by individuals in the course of their daily lives given that the proposed assessment measures and the intervention (screening/referral) have been previously used in the general population with no reported consequences. Nevertheless, we have considered the following potential risks:

*Presence of partner or other accompanying companions at time of recruitment:* To eliminate this risk, RAs will ask any companions to remain in the waiting room to maintain the participants' privacy. If this is not possible, the patient will not be allowed to participate in the study.

*Presence of other household members during the telephone interview:* To minimize this risk, 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 confidentially. 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.

*Respondent is upset by the questions.* It is possible that participants may feel emotionally uncomfortable responding to some of the questions. At time of enrollment, participants will be informed that they may skip any question they do not wish to answer, and that they are free to withdraw at any time. At wrap-up of enrollment session, RAs will ask participants how they are and if a participant feels distressed or appears distressed, the field supervisor will be available to talk to her. For the CATI, interviewers will be made aware of the sensitive nature of the questions during training and will be taught to respond respectfully and empathetically. The HCIP number and the National Domestic Violence Hotline number will be provided to **all** interviewees should they desire help for themselves or someone they know.

*Occurrence of IPV during an interview.* The chances of this event occurring during this 20-minute interview are very low. However, to further minimize this risk, interviewers will have taken the necessary precautions to make sure other members of the household are not present during the interview (see section on *Presence of other household members during the interview* above). In addition, if an interviewer hears noise (i.e., an adult speaking loudly or shouting in anger) that alert her to the possibility of a problem, they will instruct the respondent to hang up and call someone if they think they need help, or if they prefer the interviewer will call someone such as the local police to help them.

#### *Anticipated benefits*

The proposed interventions may be of benefit to some participants, and even if the interventions do not directly benefit participants, the findings will help CDC, IPV advocacy groups, and health care providers make informed decisions about the usefulness of universal screening in primary care.

The telephone interview might generate awareness and interest around the issue of IPV. All interviewees will be given the local as well as the city of Chicago Domestic Violence Hotline number should they know of anybody who might need some assistance or if they personally would like more information or assistance.

#### *Procedure for obtaining informed consent*

Patients verified to be eligible for enrollment will undergo the process of informed consent with a trained research assistant. The consent script has been written at a 7.9 grade level, based on the Flesch-Kincaid Readability Test. It 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 to respond to any or all questions; assure the respondent that the information she provides will remain confidential; that participation is voluntary, and that she will be assigned randomly to one of three groups. Potential participants will be given an opportunity to ask questions or have something they did not understand clarified and will be offered a copy of the consent form if they feel it would not put them at risk. Respondents will be given a toll free phone number to contact the PI in the event they have questions regarding the study or the agency and a local and CDC Human Subjects number if they wish information on their rights as human subjects. (See consent script in Appendix). Patients who choose not to participate will receive the usual standard of care.

#### *Provisions for protecting confidentiality*

Identifying information will be collected during the wrap-up for one-year 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. 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. All personnel, from recruiters to project director, will be required to sign confidentiality 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. Project staff will be vigilant of laptop computers while they are being used. Electronic files with the baseline and one-year follow-up interviews will be secured in computers that are password protected and kept in a locked office 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. Diskettes and other backup materials will also be stored in locked files. Contact information will be stored in lockable file cabinets.

Data extracted from the electronic medical record database for the three-year follow-up will be stored on a zip drive in an encrypted format. This database will be in an Access format and loaded onto a single stand alone PC and then de-identified (unique study ID #s only). Access to that PC will be limited and physical protections will be put in place.

Death certificates obtained for the two-year follow-up will be kept in a locked file cabinet in a locked study office and access will be limited to 2 investigators and the project coordinator. All certificates will be destroyed once data are abstracted and analyses completed.

#### Handling of Unexpected or Adverse Events

Problems or unanticipated events arising during the recruitment interview or follow-up interview will be detected by field staff and recorded in their daily logs. These will be reviewed each day by the supervisor to identify and solve any emerging problems.

## **Appendices**

## **Recruitment Flyer- ENGLISH**

**Would you like to volunteer for a study  
while you wait for your doctor or after you see your doctor today?**

We are trying something new -asking health questions on **easy-to-use** computers.

The computers can be used while you are waiting for your appointment(s) or medicine refills.

You do not need to have any computer skills.

You will listen thru headphones and touch the screen with your finger to answer the questions.

Your time with your doctor will not be affected.

For this study, the computer will ask questions about women's health.

If you are interested in knowing more – please place this paper in the bin on the reception desk. The bin is near the battery container and labeled "Women's Health and Computer Study".

You will receive compensation for your time.

If you are not interested, you may give this paper to the receptionist when you 'check out'.

**THANK YOU!**

## **Recruitment Flyer- SPANISH**

**¿Le gustaría ser una voluntaria para un estudio mientras espera a su médico o después de ver a su médico hoy?**

Estamos intentando algo nuevo - hacer preguntas de salud en computadoras que son **fáciles de usar**.

Las computadoras pueden ser utilizadas mientras espera su cita(s) o el surtido nuevo de medicamentos.

Usted no necesita tener ninguna habilidad con la computadora.

Usted escuchará por audífonos y tocará la pantalla con su dedo para contestar las preguntas.

Su tiempo con su médico no será afectado.

Para este estudio, la computadora le hará preguntas sobre la salud de las mujeres.

Si usted está interesada en saber más - por favor ponga esta hoja en la bandeja del escritorio de recepción. La bandeja está cerca del recipiente de batería y marcado "Estudio Sobre la Salud de las Mujeres por Computadora".

Usted recibirá compensación por su tiempo.

Si usted no está interesada, déle a la recepcionista esta hoja cuando termine.

**¡GRACIAS!**

## Script for Eligibility

Hi, I'm \_\_\_\_\_. I work for the Research Collaborative Unit at Stroger Hospital.

Do you speak English?

(If no) → Spanish?

(If no) → That's o.k. Thank you. →STOP

(If yes) → Muy bien. Gracias. Estamos haciendo un estudio sobre la salud de las mujeres. Tiene acceso a un teléfono a donde la podemos llamar para hacerle unas preguntas?

(If no) → No importa. Gracias. →STOP

(If yes) → Muy bien. Gracias.

(If yes) → Great. Thank you. We're doing a study on women's health.

Do you have access to a phone where we can call you to ask you some questions?

(If no) → That's o.k. Thank you. →STOP

(If yes) → Good. Thank you.

*Research Assistant will determine, by observation, if patient is ineligible because of visual, hearing, or mental impairment; or accompanied by a child over age three with no other adult supervision or a companion who refuses to separate from her.*

*(If not eligible) Patient will be thanked.*

*(If eligible) We'd like to invite you to participate in our study/Queremos invitarla a que participe en este estudio. → (Continue with consent form).*

INFORMED CONSENT FOR RESEARCH  
**Women's Health and Computer study**

*INTRODUCTION*

This is to ask you to be in a research study. This study is to find out if asking women about their health and giving information on what to do about certain risks can improve women's health. Doctors and their staff at John H. Stroger Hospital are doing this study. The study is being sponsored by the Centers for Disease Control and Prevention (CDC).

*WHAT WILL I BE ASKED DO IF I AM IN THE STUDY?*

Being part of the study means that:

1. You will be put in one of 3 options. If you decide to be in this study you will be put into one of the options by chance, like flipping a coin. Neither you nor the study staff may choose which option you are in.
2. You will hear and read questions on a computer in each of the 3 options and answer by touching the screen. The interview will last anywhere from 15-30 minutes and will take place in the clinic. In all 3 groups, the computer will ask you questions about your physical and mental health, the number of days that you were too ill to work, how often you use health care services, and questions on how to best contact you. The difference between the 3 options is that in some you may be asked about your experiences with violence and in some you may be given information on useful resources for dealing with health problems, including violence. Research staff will be available to help you if you have any questions or need help with the computer.
3. In a year, we will call you to ask you some of the same questions again over the phone. That interview will take about 20 minutes and will include questions on your experiences with violence. You can call us at 1-312-864-3684 at a time that is best for you. We can also call you if you would like. In addition, we will try to contact you at least once and possibly one or two more times to remind you about the phone interview. We would do this by either calling you or sending reminders in the mail. We will refer to this study as the "Women's Health and Computer Study" when we contact you.

*WHAT ARE THE RISKS OF BEING IN THIS STUDY*

You will be asked questions about your physical health, emotional health, ability to work, and your experience with partner violence. This may cause you to be upset. You will be interviewed 1 year later by phone and you will be asked if there is enough privacy to be sure that your answers are not heard by other members of your home. Members of your home may also know about the reminder calls or mailings. We are asking for your permission to review your medical records. In addition, there is a small chance of possible loss of privacy, but we have strict procedures to prevent that from happening. Your answers will not have your name on them but will have a code number to keep your answers separate from everybody else's. Your answers to these questions will not be shared with anyone outside of the study team.

We keep all information locked in our offices and you will never be identified in any report. We will keep your records private as much as allowed by law. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Officials from the hospital or the government may check the records to make sure your rights are protected.

*WHAT ARE THE BENEFITS TO TAKING PART IN THIS STUDY*

We hope that being in the study will be good for you, however we don't know if this will be the case. We hope that this study will show us better ways to ask women in clinics about their health.

*WHY WOULD THE DOCTORS TAKE ME OFF THIS STUDY EARLY?*

The study doctors may stop you from taking part in this study at any time if they decide it is in your best interest, if they decide it is dangerous for you to continue, or if the study is ended.

*WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?*

You can choose freely not to be in this project. The decision is up to you. The project begins in the clinic after you agree to participate and ends once all the study information is collected. You have the right to refuse to answer any of the questions during the interviews or stop the interview at any time. You have the right choose the best time for the phone interview.

If you choose *not* to be in the project, you will receive the care that you and your doctor agree on. You can also drop out of the project at any time without penalty.

*WHAT ARE THE COSTS TO ME?*

There is no cost for the study related activities.

*WILL I RECEIVE ANY COMPENSATION?*

For your time and effort, each person in the project will be given \$20 after the first interview is completed. You will then be mailed a \$15 money order, 1 year later, after the phone interview is completed.

\_\_\_ The study has been explained to me, and I agree to take part in the study on women's health.

\_\_\_ I know that I have a choice. I can choose not to be in the study, and I can choose to stop at any time during the study.

Participant's Name: (Please Print) \_\_\_\_\_

Participant's Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Person who read the consent form, explained the study in detail, and answered all questions to the subject's complete satisfaction:

Name: (Please Print) \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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You can choose to receive a copy of this form or we can just give you information on how to contact us if you have any questions.

***WHAT DO I DO IF I HAVE ANY QUESTIONS OR PROBLEMS***

You can call the project staff at 1-312-864-3684. You can leave a message here Monday-Friday 9-5 and someone will get back to you.

You can also speak with any of the following doctors:

Romina Kee	312-864-3630	Doctor, Co- Investigator
Sabrina Kendrick	312 -572-4710	CORE Center Doctor
Laura Sadowski	312-864-3646	Doctor, Principal Investigator

In addition, you can contact the Quality Coordinator (Funeka Sihlali) about your rights as a participant or if you feel that you have been harmed in any way at 312-864-4821 during business hours or the CDC Human Research Protection Office at 1-800-584-8814. For the CDC, leave a brief message with protocol number 4985, your name, and phone number, and you will be called back as soon as possible.

## SPANISH VERSION OF CONSENT FORM

### CONSENTIMIENTO INFORMADO PARA INVESTIGACIÓN

#### **Estudio Sobre la Salud de las Mujeres por Computadora**

#### *INTRODUCCIÓN*

Esto es para pedirle que sea parte de un estudio. El propósito de este estudio es para saber si preguntándole a las mujeres sobre su salud y dándole información sobre qué hacer frente a ciertos riesgos mejora su salud. Los doctores y su personal en el hospital de John H. Stroger están haciendo este estudio. El estudio está siendo patrocinado por los Centros para el Control y la Prevención de Enfermedades (CDC).

#### ¿QUÉ TENGO QUE HACER SI ESTOY EN EL ESTUDIO?

Ser parte del estudio significa que:

1. Usted será asignada a una de 3 opciones. Si usted decide estar en este estudio, usted será asignada a una de estas opciones al azar, como echar una moneda a cara o cruz. Ni usted ni el personal del estudio puede elegir a cual grupo será asignada.
2. Escuchará y leerá preguntas en una computadora en cada uno de las 3 opciones, y contestará tocando la pantalla. La entrevista durará entre 15-30 minutos y ocurrirá en la clínica. En los 3 grupos, la computadora le preguntará acerca de su salud física y mental, el número de días que no pudo trabajar por incapacidad, la frecuencia con que usted utiliza los servicios de asistencia médica, y preguntas sobre la mejor manera de contactarla. La diferencia entre las tres opciones es que algunos quizás se le preguntará sobre sus experiencias con la violencia y en otros quizás se le dará información sobre los recursos útiles para hacerle frente a los problemas de salud, incluyendo la violencia. Personal del estudio estará disponible para ayudarle por si tiene preguntas o necesita ayuda con el computador.
3. En un año, le haremos algunas de las mismas preguntas por teléfono. Esa entrevista tomará cerca de 15-20 minutos e incluirá preguntas sobre su experiencia con la violencia. Usted también puede llamarnos al 1-312-864-3684 a una hora que le conviene. O si prefiere, nosotros la podemos llamar. Durante el año, nosotros trataremos de contactarla por lo menos una vez y posiblemente una o dos veces más para recordarle sobre la entrevista por teléfono. Haremos esto ya sea llamándole o enviándole recordatorios por correo. Nos referiremos a este estudio como el “Estudio Sobre la Salud de las Mujeres por Computadora” cuando nos comuniquemos con usted.

#### ¿CUÁLES SON LOS RIESGOS DE SER PARTE EN ESTE ESTUDIO?

Le harán preguntas sobre su salud física, salud emocional, capacidad de trabajar, y su experiencia con la violencia de pareja. Esto puede causarle molestia. Usted será entrevistada 1 año después por teléfono y hay un riesgo que otros miembros de su hogar puedan oír por casualidad sus respuestas. Los miembros de su hogar también pueden saber sobre las llamadas o los recordatorios por correo. También le estamos pidiendo su permiso para revisar sus expedientes médicos. Hay una pequeña posibilidad de la posible pérdida de privacidad pero tenemos procedimientos estrictos para prevenir que eso vaya a suceder. Sus respuestas no tendrán su nombre en ellas pero sí tendrán un número de código para mantener sus respuestas separadas de todas las demás. Sus respuestas a estas preguntas no serán compartidas con otros fuera del estudio.

Mantenemos toda la información asegurada en nuestras oficinas y nunca será identificada en ningún informe. Mantendremos su información en privado hasta donde la ley no lo permite. Su nombre y otros hechos que podrán identificarla no aparecerán cuando presentamos este estudio o publicamos los resultados.

Los oficiales del hospital o del gobierno pueden verificar los expedientes para asegurar que sus derechos están protegidos.

#### ¿CUÁLES SON LOS BENEFICIOS DE SER PARTE EN ESTE ESTUDIO?

Esperamos que el estar en el proyecto sea bueno para usted, pero no sabemos si esto será el caso. Esperamos que este estudio nos muestre mejores maneras de preguntarles a las mujeres en las clínicas sobre sus asuntos de salud.

#### ¿POR QUE LOS DOCTORES ME TOMARIAN DE ESTE ESTUDIO TEMPRANO?

Los doctores del estudio pueden parar su participación en este estudio en cualquier momento si ellos deciden que está en su mejor interés, si deciden que es peligroso para usted continuar, o si el estudio se termina.

#### ¿CUÁLES SON MIS DERECHOS COMO PARTICIPANTE EN LA INVESTIGACIÓN?

Usted puede elegir libremente no estar en este proyecto. La decisión es suya. El proyecto empezará en la clínica después de que usted esté de acuerdo en participar y terminará cuando toda la información del estudio sea recolectada.

Usted tiene el derecho de negarse a contestar cualquier pregunta durante las entrevistas o de parar la entrevista en cualquier momento. Usted tiene el derecho de elegir el mejor momento para la entrevista por teléfono.

Si usted elige *no* estar en el proyecto, usted recibirá el cuidado que usted y su doctor acuerden. Usted también puede retirarse del proyecto en cualquier momento sin castigo.

#### ¿CUÁLES SON LOS COSTOS PARA MÍ?

No hay costo para las actividades relacionadas al estudio.

#### ¿VOY A RECIBIR ALGUNA COMPENSACIÓN?

Por su tiempo y esfuerzo, cada persona en el proyecto recibirá \$20 después de que la primera entrevista se ha completado. Luego se le enviará un giro postal de \$15, 1 año más tarde, después de que la entrevista por teléfono se ha completado.

\_\_\_\_\_ Se me ha explicado el estudio, y estoy de acuerdo en tomar parte en el estudio sobre la salud de las mujeres.

\_\_\_\_\_ Sé que puedo elegir. Puedo elegir no estar en el estudio, y puedo elegir parar en cualquier tiempo durante el estudio.

Nombre del Participante: (Favor de usar letra de imprenta) \_\_\_\_\_

Firma del Participante: \_\_\_\_\_

Fecha: \_\_\_\_\_

Persona que leyó el consentimiento, explicó el estudio en detalle, y contestó todas las preguntas a la satisfacción completa del participante:

Nombre: (Favor de usar letra de imprenta) \_\_\_\_\_

Firma: \_\_\_\_\_

Fecha: \_\_\_\_\_

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Usted puede elegir si recibir una copia de este consentimiento o le podemos dar la información sobre cómo contactarnos si usted tiene algunas preguntas.

¿QUÉ HAGO SI TENGO ALGUNAS PREGUNTAS O PROBLEMAS?

Usted puede llamar el personal del proyecto al 1-312-864-3684. Puede dejar un mensaje aquí de lunes-viernes de 9-4 y alguien se pondrá en contacto con usted.

También puede hablar con cualquiera de los siguientes doctores:

Romina Kee	312-864-3630	Ob/Gin	Doctora
Sabrina Kendrick	312-572-4710	Centro CORE	Doctora
Laura Sadowski	312-864-3646	Atención Primaria	Doctora, Investigadora Principal

En adición, puede contactar a la Coordinadora de Calidad (Funeka Sihlali) acerca de sus derechos como participante al 312-864-4821 durante las horas de oficina, lunes-viernes, o llamar a la Oficina de Protección del Participante en la Investigación del CDC al 1-800-584-8814. Para el CDC, deje un breve mensaje con el número del protocolo # 4985, su nombre, y el número de teléfono, y alguien le devolverá la llamada lo mas pronto posible.

Printouts for IPV (+) and IPV (-) women

Our patients have found these places to provide helpful health and social services to those who live in Cook County.

**List of contacts**

Stroger Hospital Crisis Intervention (HCIP).....312-864-1095

Humboldt Park Outreach Program (HPOP).....773-489-9081

National Domestic Violence 24hr Hotline (Toll Free).....1-800-799-SAFE

Chicago Domestic Violence Helpline (Toll Free).....877-863-6338

IL Domestic Violence 24hr Hotline (Toll Free) .....1-800-603-HELP

City of Chicago 24 hr Suicide Hotline (Toll Free).....1-800-273-TALK

Chicago Department of Human Services (Toll Free)...1-800-654-8595

Chicago Department of Health .....312-744-5000

Infant Welfare Society.....773-782-2800

Stroger Hospital.....312-864-6000

Provident Hospital.....312-572-2000

Core Center.....312-572-4500

Rush University Medical Center .....312-942-5000

**Parenting Support**

Action for Children.....773-687-4000

Howard Area Community Center .....773-262-6622

Metropolitan Family Services .....312-986-4000

Salvation Army Family Services .....773-275-6233

Christopher House.....773-472-1083

**Counseling Services**

National Alliance for the Mentally Ill (Toll Free).....1-800-950-6264

Community Counseling Centers of Chicago.....773-769-0205

Miles Square.....312-850-5800

Mujeres Latina en Acción .....773-890-7676

Rainbow House Outreach Center .....773-521-1815

**Legal Services**

Cook County State's Attorney/Victim Witness Assistance.....773-869-7200

First Defense Legal Aid (Toll Free).....1-800-LAWREP4

**Emergency Shelters**

Apna Ghar.....(North) 773-334-0173

.....(South) 773-334-4663

Family Rescue (Southwest) .....773-375-8400

Greenhouse (Northside) .....773-278-4566

Crisis Center South Suburbia .....708-429-7233

Elgin-Battered Women's Shelter .....847-697-2380

Evanston-Battered Women's Shelter .....847-864-8780

Sarah's Inn.....708-386-4225

**Alcohol/Drug Treatment Services**

Alcohol/Drug 24hr Helpline (Toll Free).....1-800-821-4357

Alcoholic Anonymous 24hr (Toll Free).....1-800-371-1475

Haymarket Center.....312-226-7984

Women's Treatment.....312-633-4972

Gateway Foundation .....773-890-5667

Cornell Intervention... ..773-737-4600

New Horizon Rehab .....773-261-6663

Association House.....773-772-8009

Our patients have found these places to provide helpful health and social services to those who live in Cook County.

### **List of Contacts**

Stroger Hospital.....312-864-6000

Provident Hospital.....312-572-2000

Core Center.....312-572-4500

Rush University Medical Center  
.....312-942-5000  
Chicago Dept of Health  
.....312-744-5000

Illinois Department of Human Services  
(Toll Free).....1-800-843-6154

Chicago Department of Human  
Services (Toll Free).....1-800-747-0200

Infant Welfare Society.....773-728-2800

Department of Human Services  
(Toll Free).....1-800-654-8595

### **Legal Services**

Cook County State's Attorney/Victim  
Witness Assistance.....773-869-7200

First Defense Legal Aid  
(Toll Free).....1-800-LAWREP4

### **Counseling Services**

Rainbow House Outreach Center  
(Toll Free).....1-800-913-0065

National Alliance for the Mentally Ill  
(Toll Free).....1-800-950-6264

Miles Square.....312-850-5800

Community Counseling Centers of  
Chicago.....773-769-0205

Mujeres Latina en Acción  
.....773-890-7676

### **Parenting Support**

Action for Children.....773-687-4000

Christopher House.....773-472-1083

Howard Area Community Center  
.....773-262-6622

Metropolitan Family Services  
.....312-986-4400

Salvation Army Family Outreach  
.....312-733-0500

### **Alcohol/Drug Treatment Services**

Alcohol/Drug 24hr Helpline  
(Toll Free).....1-800-821-4357

Alcoholic Anonymous 24hr  
(Toll Free).....1-800-371-1475

Haymarket Center.....312-226-7984

Women's Treatment.....312-633-4972

Gateway.....773-890-5667

Cornell Intervention.....773-737-4600

New Horizon Rehab .....773-261-6663

Association House.....773-772-8009

### **Emergency Shelters**

Apna Ghar.....(North) 773-334-0173  
.....(South) 773-334-4663

Family Rescue (Southwest)  
.....773-375-8400

Greenhouse (Northside)  
.....773-278-4566

Crisis Center South Suburbia  
.....708-429-7233

Sarah's Inn.....708-386-4225

## Questionnaires

Baseline Measures

**A. Quality of Life: SF-12 Health Survey** (Ware, Kisinski, & Keller, 1996)

These first questions ask about your health and how well you get along in your usual activities. For each question please touch the one box the best describes you.

Delayed CASI response for patients who haven't answered within 5 seconds of completion of question: "If you are unsure about how to answer, please choose the box that seems best for you."

1. In general, would you say your health is:

Excellent     Very good     Good     Fair     Poor

Now a list of activities you might do in a typical day will be read. As each item is read, please indicate if your health now limits you a lot, limits you a little, or not at all in these activities.

2. Moderate activities such as moving a table, pushing a vacuum cleaner?	Yes, limited a lot <input type="checkbox"/>	Yes limited little <input type="checkbox"/>	No, not limited at all <input type="checkbox"/>
3. Climbing several flights of stairs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*The following 2 questions ask about your physical health and your daily activities.*

4. During the past 4 weeks, how much of the time have you accomplished less than you would like as a result of your physical health?

all of the time  
 most of the time  
 some of the time  
 a little of the time  
 none of the time

5. During the past 4 weeks, how much of the time were you limited in the kind of work or other regular daily activities as a result of your physical health?

all of the time  
 most of the time  
 some of the time  
 a little of the time  
 none of the time

*The next 3 questions ask about your emotions and your daily activities.*

6. During the past 4 weeks, how much of the time have you accomplished less than you would like as a result of any emotional problems (such as feeling anxious or depressed)?

- all of the time
- most of the time
- some of the time
- a little of the time
- none of the time

7. During the past 4 weeks, how much of the time did you do work or other daily activities less carefully than usual as a result of any emotional problems (such as feeling anxious or depressed)?

- all of the time
- most of the time
- some of the time
- a little of the time
- none of the time

8. During the past 4 weeks, how much did pain interfere with your normal work including both work outside the home and housework?

Not at all    A little bit    Moderately    Quite a lot    Extremely

                                                                                      

These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the last 4 weeks:

	All of the time	Most of the time the time	A good bit of	Some of the time the time	A little of	None of the time
9. Have you felt calm and peaceful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Have you felt downhearted and blue?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. During the last 4 weeks, how much of the time has your physical health or emotional problems interfered with your usual activities (like visiting friends, relatives, etc.)?

All of the time    Most of the time    Some of the time    A little of    None of the  
the time                      time

### **B. Disability**

1. During the 30 days from { date from 30 days before baseline interview to baseline interview }, about how many days did you miss work because of an illness or injury (do not include maternity leave)? If patient delays answer, audio cues for patient to give best guess.

- \_\_\_ days
- \_\_\_ Don't remember
- \_\_\_ Don't work outside the house

2. During the 30 days from { date from 30 days before baseline interview to baseline interview }, about how many days were you unable to do your housework tasks because of an illness or injury (do not include maternity leave)?

- \_\_\_ days
- \_\_\_ Don't remember

### **C. Current signs or symptoms**

<b>Are you frequently bothered by any of the following problems?</b>			
1. Arthritis or pain, aching, stiffness, or swelling in or around a joint (knee, elbow, hip, fingers, etc.)	YES	NO	
2. Neck pain or low back pain	YES	NO	
3. Stomach or abdominal pain	YES	NO	
4. Menstrual cramps or other problems with your periods	YES	NO	I am not having periods now
5. Pain or problems during sexual intercourse	YES	NO	I am not having sex now
6. Vaginal bleeding that is not normal	YES	NO	
7. Vaginal or genital infection or any kind of discharge	YES	NO	
8. Headaches or migraines	YES	NO	
9. Nausea, gas, or indigestion	YES	NO	
10. Constipation	YES	NO	
11. Vomiting or diarrhea	YES	NO	
12. Trouble falling asleep or staying asleep on 3 or more	YES	NO	

nights a week.			
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**D. Health Care Utilization outside Bureau**

1. During the past 12 months, have you stayed at least one night – not just in an emergency room hospitalized in a hospital or clinic other than at Stroger or Rush?  
\_\_\_ Yes → How many times were you hospitalized in a hospital other than Stroger or Rush? \_\_\_  
\_\_\_ No

2. During the past 12 months, have you gone to an Emergency Department Room other than at Stroger or Rush?  
\_\_\_ Yes → How many times were you in an emergency room other than Stroger or Rush? \_\_\_  
→ Were any of these times because of an injury (like a cut, burn, fracture, bloody nose or mouth)? \_\_\_ Yes \_\_\_ NO  
\_\_\_ No

**F. Partner Violence Screen** (Feldhaus, et al., 1997) **ONLY IN ARM 1**

These next questions refer to violence by intimate partners. Violence is a problem for many women. Because it affects their health, we are asking our patients about it. Just so you know, your answers will not be shared with anyone unless you choose to share them.

1. Have you been hit, kicked, punched, or otherwise hurt by an intimate partner within the past year?  
\_\_\_ YES  
\_\_\_ NO
2. Do you feel safe in your current relationship?  
\_\_\_ YES  
\_\_\_ NO
3. Is there a partner from a previous relationship who is making you feel unsafe now?  
\_\_\_ YES  
\_\_\_ NO

One-year Follow-up Measures

**A. Quality of Life SF-12 Health Survey** (Ware, Kisinski, & Keller, 1996)

These first questions ask about your health and how well you get along in your usual activities.

1. In general, would you say your health is:

Excellent    Very good    Good    Fair    Poor  
               

Now a list of activities you might do in a typical day will be read. As each item is read, please indicate if your health now limits you a lot, limits you a little, or not at all in these activities?

2. Moderate activities such as moving a table, pushing a vacuum cleaner	Yes, limited a lot <input type="checkbox"/>	Yes limited little <input type="checkbox"/>	No, not limited at all <input type="checkbox"/>
3. Climbing several flights of stairs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*The following 2 questions ask about your physical health and your daily activities.*

4. During the past 4 weeks, how much of the time have you accomplished less than you would like as a result of your physical health?

- all of the time
- most of the time
- some of the time
- a little of the time
- none of the time

5. During the past 4 weeks, how much of the time were you limited in the kind of work or other regular daily activities as a result of your physical health?

- all of the time
- most of the time
- some of the time
- a little of the time
- none of the time

*The next 3 questions ask about your emotions and your daily activities.*

During the {date from 30 days before baseline interview to baseline interview}, have you had any of the following problems with your work or other regular daily activity as a result of your emotional problems (such as feeling depressed or anxious)?

6. During the past 4 weeks, how much of the time have you accomplished less than you would like as a result of your emotional problems (such as feeling anxious or depressed)?

- all of the time
- most of the time
- some of the time
- a little of the time
- none of the time

7. During the past 4 weeks, how much of the time did you do work or other daily activities less carefully as a result of your emotional problems (such as feeling anxious or depressed)?

- all of the time
- most of the time
- some of the time
- a little of the time
- none of the time

8. During the past 4 weeks, how much did pain interfere with your normal work including both work outside the home and housework?

Not at all    A little bit    Moderately    Quite a lot    Extremely

                                                                                      

*These questions are about how you feel and how things have been with you during the last 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during these dates:*

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Did you feel calm and peaceful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Have you felt downhearted and blue?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your usual activities (like visiting friends, relatives, etc.)?



These next questions ask for your opinions about abuse by an intimate partner. Don't worry if you're not sure of the answer.

1. Please think about this situation: If there were 10 women sitting in a room, how many of these women would you guess have **ever** been physically, verbally, emotionally, or sexually threatened or harmed by an intimate partner?

\_\_\_\_\_ (number, 0-10)

2. How likely is it for women threatened or harmed by an intimate partner (compared to women who have not been threatened or harmed) to have problems with their physical health? More likely, less likely, or about the same?

- More likely  
 Equally likely  
 Less likely

3. How likely is it for women threatened or harmed by an intimate partner (compared to women who have not) to have problems with their mental health such as anxiety, depression, or substance abuse? More likely, less likely, or about the same?

- More likely  
 Equally likely  
 Less likely

4. Do you agree or disagree with this statement:

“Women usually get hurt by their partners because of something they (the women) did”?

- Agree  
 Disagree  
 Not sure

5. Do you agree or disagree with this statement: “Women who are hurt by their partners can get help if they need it”?

- Agree  
 Disagree  
 Not sure

6. Where can a woman who is being hurt by an intimate partner get help in this community? (*Do not provide options*)

- HCIP  
 Name of other local IPV resource  
 Police  
 Other

### **E. Exposure to Intimate Partner Violence** (NVAWS, 2000)

Now we would like to know about **your** experiences with intimate partners. Just so you know, your answers will not be shared with anyone unless you choose to share them.

Has a person you dated, or became romantically involved with, or lived as a couple with ever:

- |   |     |    |
|---|-----|----|
| 1. tried to limit your contact with family and friends?           | YES | NO |
| 2. been jealous or possessive?                                    | YES | NO |
| 3. insisted on knowing who you were with at all times?            | YES | NO |
| 4. called you names or put you down in front of others?           | YES | NO |
| 5. made you feel inadequate?                                      | YES | NO |
| 6. shouted or sworn at you?                                       | YES | NO |
| 7. prevented you from having access to joint income?              | YES | NO |
| 8. thrown something at you that could hurt?                       | YES | NO |
| 9. pushed, grabbed, or shoved you?                                | YES | NO |
| 10. pulled your hair?   | YES | NO |
| 11. slapped or hit you?   | YES | NO |
| 12. kicked or bitten you?   | YES | NO |
| 13. choked or attempted to drown you?                             | YES | NO |
| 14. hit you with some object?                                     | YES | NO |
| 15. beat you up?  | YES | NO |
| 16. used or threatened you with a knife?                          | YES | NO |
| 17. used or threatened you with a gun?                            | YES | NO |
| 18. made you or tried to make you have vaginal, oral or anal sex? | YES | NO |

*Skip Q 19 and 20 if 1-18 response is no or don't know (silent code).*

*If yes to any of the above ask Q19, Q20, & Q21 →*

19. Did any of these experiences you've just told me about (*interviewer repeats IPV exposure reported*). happen in the past year, that is since <insert date one year ago>?

\_\_\_ YES

\_\_\_ NO

*Silent code for Don't know/unsure*

20. Please think back to the year before we first interviewed you at <insert clinic where she was interviewed> that would be starting on <insert date one year before ACASI> and ending on <insert date of ACASI>? Did any of these experiences with an intimate partner happen during that time?

\_\_\_ Yes

\_\_\_ No

*Silent code for Don't know/unsure*

21. Have you talked to anyone about these experiences?

\_\_\_ NO → Would you like to talk to someone?

\_\_\_ *If yes* → at the end of our interview I will give you a number you can call.

\_\_\_ *If no* → just in case you change your mind, at the end of our interview, I will give you a number you can call.

\_\_\_ YES → Had you already talked to somebody before you joined this study?

\_\_\_ YES

\_\_\_ NO

## **F. Side effects**

Now we want you to think back to when you first got involved in this study.

1. A year ago {*DATE OF BASELINE*} we asked you some questions on a computer survey. Do you remember this?

\_\_\_ YES

\_\_\_ NO → *SKIP TO Q3.*

2. Because of being asked these questions, did you have any small or big problems, or no problems? *Interviewers remind answers are confidential.*

a. Big problems → What were the big problems?

b. Small problems? → What were the smaller problems?

c. Both big and small problems → What were the big problems? Smaller problems?

d. No problems at all

*(Instructions to interviewers for problems probe for free text to include- description of problems including who, what, when, etc)*

3. Do you remember if you received a list of services from the computer that time?

\_\_\_ Yes → *(continue with next question)*

\_\_\_ No → *(skip to next section)*

4. Did you share this list of services with anyone?

\_\_\_ Yes → who? *{interviewer probe relationship}*

\_\_\_ No

5. Did you use the list to contact one of the services?

\_\_\_ Yes

\_\_\_ No

6. Did you have any small or big problems, or no problems as a result of getting this list?

\_\_\_ a. Big problems → What were the big problems?

\_\_\_ b. Small problems? → What were the smaller problems?

\_\_\_ c. Both big and small problems → What were the big problems? Smaller problems?

\_\_\_ d. No problems at all

7. Before joining this study last year, had you ever called or visited an agency that provides help to women who have been abused by their intimate partner?

\_\_\_ YES

\_\_\_ NO

Thank you.

*(If respondent reported current exposure to IPV)* I promised to give you a number you can call to talk about your experiences with your partner. The number is 312-864-1095. You can also call 877-863-6338.

*(All other respondents)* Just in case you or someone you know should ever need help with domestic violence, please write down this number: 312-864-1095. They can also call 877-863-6338.

## **IPV Project**

### **Pledge of Confidentiality and Privacy**

I have read and understood the policies on the security and privacy of the information collected for Women's IPV Screening Study in Obstetrics and Gynecology Clinics. These policies are detailed in the electronically stored IRB approved Study Protocol.

I understand that all data and information to which I may have access is confidential and private and is not to be communicated to anyone in any manner, except as outlined in the policies.

I have been made aware of the possible consequences of any intentional or unintentional breach of the Security and Privacy Policy.

Printed Name \_\_\_\_\_

Signed Name \_\_\_\_\_

Date \_\_\_\_\_