Intimate Partner Violence Prevention Project
with the Raleigh/Cary Chinese Community

By

Huei-Chen Lao

A Master’s Paper submitted to the faculty of
the University of North Carolina at Chapel Hill
In partial fulfillment of the requirements for
the degree of Master of Public Health in
the Public Health Leadership Program.

Chapel Hill

2010

___________________________
Advisor signature/printed name

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Second Reader Signature/printed name

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Date
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Introduction

Our program is designed to gain qualitative information about the characteristics and risk factors associated with the Intimate Partner Violence (IPV) among the Chinese immigrants who reside in the Raleigh/Cary metropolitan area in North Carolina. IPV is the threat or use of violence or intimidation by an intimate partner to gain and maintain power and control over another person (Interact, 2009). IPV comes in many different forms, including physical abuse, sexual abuse, emotional abuse, economic abuse, isolation and intimidation. Many abusers engage in more than one type of abuse, and the boundaries between some of these types of abuse often overlap (Center for Disease Control and Prevention [CDC], 2009; Interact, 2009).

IPV can affect health in many ways. Many victims suffer physical injuries. Some are minor, such as cuts, scratches, bruises, and welts. Others are more serious and can cause lasting disabilities. These include broken bones, internal bleeding, and head trauma. IPV can also cause emotional harm. Victims often have low self-esteem and they may have a hard time trusting others and having successful relationships. The anger and stress experienced by victims may lead to eating disorders and depression. Some victims contemplate or commit suicide. IPV is linked to harmful health behaviors as well. Victims are more likely to smoke, abuse alcohol, use drugs, and engage in risky sexual activity (CDC, 2009).

IPV occurs in all countries, all cultures and at every level of society without exception (Krug, Dahlberg, Mercy, Zwi, & Lozaro, eds., 2002). Although women can be violent towards their male partners and violence also occurs between partners of the same sex, the overwhelming burden of partner violence is borne by women at the hands of men. In 48 population-based surveys from around the world, 10-69% of women reported being physically assaulted by a male intimate partner at some point in their lives (Krug et al., 2002). Although poverty and associated
stress, patriarchy, depression, and substance use/abuse have all been associated with IPV, the causes for IPV are complex and understanding the causes of such violence requires research in many social contexts (Jewkes, 2002; Riggs & Street, DS, 2000). Cross-cultural research suggests that societies with stronger ideologies of male dominance have more IPV (Jewkes, 2002). These ideologies affect individual behaviors and also have an impact at many levels within a society. At a societal level they affect female autonomy, access to political systems, and influence in the economy. Such ideologies also affect laws and criminal justice systems. For example, whether violence against women is considered a crime and treated with seriousness by law enforcers.

As with the causes of IPV, the strategies for intervention and prevention of IPV are also complex and need to be developed from a socio-ecological perspective. Female empowerment has been shown to be protective against IPV. For example, a study by Parker et al. (Parker, McFarlene, Soeken, Silva, & Reel, 1999) demonstrated that intervention using empowerment as the framework significantly reduced the incidence of IPV. Empowerment interventions include (a) protection—a focus on increasing the woman’s safety and (b) enhanced choice-making and problem-solving in decisions about the relationship, relocation, and other transitional issues. At the individual level, this model emphasizes that the woman, as the victim of IPV, can make decisions and collaborate with others to solve her dilemma, thus allowing the woman to express her feelings to a nonjudgmental and empathetic person, and make her own decisions about the future.

Female empowerment can also be derived from interpersonal, community, and institutional sources such as social/community support, education, and legislative action. Education confers empowerment via social networks, self-confidence, and an ability to use
information and resources available in society. Multiple studies have indicated that high educational achievement by women is associated with low levels of violence (Jewkes R, 2002; Thompson et al., 2006; Maziak, 2002, Lancet). The following is a brief list of IPV intervention and prevention strategies based on the Socio-Ecological Model (SEM):

At the social/community level:

- Address gender issues, violence, and non-violent conflict resolution in school and community programs
- Support community activities and campaigns in the media to increase awareness of violence against women
- Positive role modeling of women in the media

At the institute level:

- Establish comprehensive legislation on gender equality, IPV, and sexual violence/harassment
- Train and monitor the police and criminal justice system to ensure that legislation is satisfactorily enforced
- Improve opportunities for women’s employment and access to credit

IPV is a serious social and public health problem which causes physical injuries and psychological harm to the victims. In the United States, IPV was first identified as a national problem four decades ago by feminist movement (Kilpatrick, 2004), and has since gained increasing interest in its intervention and prevention. However, studies on IPV in Asian American population or its ethnic subgroups have been scarce. The purpose of our program is to obtain qualitative, culture-related IPV data from the Chinese immigrants who reside in the Raleigh/Cary metropolitan area in North Carolina. Not only will this information provide us a
preliminary description of the nature of IPV in this community, more importantly, it could guide us to form hypotheses and develop programs which will increase the awareness and promote the prevention of IPV among this population.

**Study Design and Methods**

In traditional Chinese families, family structure is hierarchical and patriarchal, which legitimizes men’s control of women. Even though China has little notion of individual privacy, violence against a woman by her husband is generally concealed and protected within the sphere of private life and is largely overlooked and ignored (Xu et al., 2005). The few studies that have been conducted found that 20-30% of Chinese women have been physically abused by their spouses (Xu et al., 2005; Parish, Wang, Laumann, Pan, & Luo, 2004). However, it is difficult to estimate the prevalence of IPV in China because the Chinese have different definitions of abuse (Midlarsky, Venkataramani-Kothari, & Plante, 2006), and generally do not consider psychological and verbal ill-treatment as abusive. For example, if a Chinese woman is belittled by her husband, her earnings are taken from her and she is locked in the house when she is not at work, her community will not view her husband’s behavior as abusive (Midlarsky et al., 2006).

There are approximately 2.4 million ethnic Chinese living in the United States (US Census Bureau, 2010). Chinese Americans constitute the largest portion of the Asian American population, comprising more than 23% of the group. The size of the Chinese American population today is probably underestimated in the official census data due to the number of new immigrants who prefer to remain undocumented for legal, financial, and other reasons. As in most immigrant groups, Chinese immigrants experience great individual, cultural, and family stress in the process of transition and acculturation (Leong, 2001), which plays a role in IPV. A
good example is that Chinese immigrant couples find themselves in a new culture that has different gender role expectations than their culture of origin, which can cause changes in the power balance in couples (Jin & Keat, 2010).

Chinese society is typically more patriarchal than American society, and Chinese men tend to enjoy a power imbalance in their favor in marriages (Chan & Leong, 1994). In the United States, Chinese men may find their traditional position within the couple challenged (Jin & Keat, 2010). Language problems or a different professional structure in the U.S. may restrict a husband’s employment options, while the cultural expectation that he provide for his family may remain the same. At the same time, wives who played a less prominent role outside the home in China may become an indispensable part of the workforce in the U.S., so their individual socioeconomic power could rise post-immigration. Women’s relatively low socioeconomic status in their homelands may make it easier for them to cope in the new country because they are less likely to experience a relatively unskilled job as a loss or denigration. Social support in the U.S. for more equality within couples may also shift the female role to one of greater power post-immigration (Liao, 2006), which further upsets the balance in the family and increases the likelihood of IPV.

We chose the Chinese in the Raleigh/Cary area as the target population for our study because this is a fast growing area with a steady inflow of immigrants. According to the U. S. Census Bureau, Raleigh/Cary saw its population climb 4.3% between July 1, 2007, and July 1, 2008, to 1.1 million, which makes it the nation’s fastest-growing metro area between 2007 and 2008 (U. S. Census Bureau, 2010). There are estimated six thousand Chinese in the Raleigh/Cary, NC (Cary, North Carolina, 2010; Raleigh, North Carolina, 2010) area, and we will recruit study participants through the following avenues:
• Through collaboration with the Triangle Area Chinese American Society (TACAS): TACAS is a non-political, non-profit organization, and is one of the biggest and most established Chinese organizations in the Research Triangle area which covers Raleigh and Cary. TACAS was founded in 1979 with the missions of fostering the Chinese-American cultural exchange, promote Chinese language and cultural education, and participate in public welfare and community services. TACAS is dedicated to community services and co-organizes Asian American Health Fair, Immigration seminar, and provide resources to charity and local activities. We will distribute flyers during TACAS events; advertise on the TACAS Newsletters and website, http://www.nctacas.org/.

• Pamphlets and flyers will be given at the Grand Asia Market (GAM) located in Cary, North Carolina. GAM is the biggest Chinese Grocer in the Triangle area and is the major store for the local Chinese to get Asian groceries; it has also been utilized by various community groups to distribute information about their activities and services. With all the foot traffic in GAM, we believe we should be able to promote our program and generate interest for participation.

The inclusion criteria for study participants include: Chinese immigrants, female, 18 years of age or older, English-speaking, married or having been in a relationship with a man. Our goal is to form at least two focus groups with six participants per group. A focus group is a form of qualitative research in which a group of people are asked about their perceptions, opinions, beliefs and attitudes towards a product, service, concept, advertisement, idea, or packaging (Focus group, 2010). Focus groups provide the opportunity to gain information in a semi-structured group discussion format, and have become an increasingly common research method. Focus groups do not follow a rigid question-and-answer format. Instead, questions are
identified by the group facilitator and are used to begin the process and to move the discussion along. For the most part, the specific content addressed, the order of the content, and the specificity provided is determined by the group’s participants. Such methods are extremely useful in exploratory work where an investigator is not testing specific hypotheses or making precise measurements of a phenomenon but is trying to learn more about a previously understudied topic. Also, group members discover a common language to describe similar experiences, and this enables the capture of a form of “native language” to understand the situation (Focus group, 2010).

Focus groups in our program will be facilitated by Huei-Chen Lao, under the guidance of Mrs. Ritu Kaur, the Associate Director of Community Relations at Interact of Wake County. Interact is “a private, non-profit, United Way agency that provides safety, support, and awareness to victims and survivors of domestic violence and rape/sexual assault. Interact also promotes violence-free relationships and communities through collaboration, public information, education and advocacy.” (http://www.interactofwake.org/).

Huei-Chen Lao has been a volunteer for Interact Speakers’ Bureau since 2008 and she has given presentations to various groups and local organizations. She has also facilitated children’s groups. Huei-Chen will prepare questionnaires and have them reviewed by Mrs. Kaur before focus groups start. Questions that are focused on three themes will be presented to the participants to elicit discussion: (1) Perceptions about IPV—How does each participant perceive and understand IPV as an individual and where does this understanding come from? (2) What are the influences of specific elements of culture regarding IPV? Discuss the cultural and religious practices, family rituals, gender roles, and the functions of individuals and groups related to IPV. (3) What is the awareness of and access to agencies that intervene and provide
services to IPV victims and survivors, such as Interact, that participants have? A display for Interact will be set up for the focus groups and it includes the information about the confidential and free services provided by Interact such as 24 hour Crisis-Lines, Youth Education Services, Counseling, Residential Shelter, and Rape prevention Education.

**Ethical Concerns**

It is very important that we are familiar with the specific ethical issues raised by work that involves IPV. A World Health organization (WHO) report, Putting Women First: Ethical and Safety Recommendations for Research on Domestic Violence against Women (Putting Women First, 2001), highlights the need for specific precautions in undertaking such research—“Research on violence against women raises important ethical and methodological challenges in addition to those posed by any research. The nature of the topic means that issues of safety, confidentiality and interviewer skill and training are even more important than for other areas of research. It is not an exaggeration to say that the physical safety and psychological well-being of both the respondents and the research team can be put in jeopardy if adequate precautions are not taken.” (Putting Women First, 2001)

We will abide by the guidance given in this report to guard the study participants from any harm. For example, a number of mechanisms are recommended to protect the confidentiality of the information collected, including:

- No names should be written on questionnaires. Instead, unique codes should be used to distinguish questionnaires. Where identifiers are needed to link a questionnaire with the household location or respondent, they should be kept separately from the questionnaires,
and upon completion of the research, destroyed. Participants should be informed of confidentiality procedures as part of the consent process.

- Where tapes are made of in-depth interviews with survivors of violence, these should be kept in a locked cabinet with limited access, and erased following transcription. The permission of the respondents should be sought before taping.

- Particular care should be taken during the presentation of the research findings that the information presented is sufficiently aggregated to ensure that no one community or individual can be identified. Where case-study findings are presented, sufficient detail should be changed to ensure that it is not possible to identify the source of this information.

This report also provides guidelines to reduce any possible distress caused to participants by the research. Domestic violence is a sensitive and stigmatized issue, and women are often blamed for the violence they experience. Therefore all questions about violence and its consequences should be asked in a supportive and non-judgmental manner. In addition, some women may become emotional during a discussion or an interview, and interviewers need to be trained to be aware of the effects that the questions may have on the informant and how best to respond, based on the woman’s level of distress. All interviews should end in a positive manner and interviewer training needs to include practice on how to terminate an interview if the impact of the questions becomes too negative.

In addition, an application for the Institutional Review Board (IRB) Approval of Human Subjects Research will be sent to the Office of Human Research Ethics at University of North Carolina at Chapel Hill. The purpose of the IRB review is to assure that appropriate steps are taken to protect the rights and welfare of human participants as subjects in a research study.
Research protocols and related materials such as informed consent documents will be submitted to the review committee to ensure protection of the rights and welfare of human subjects of research.
APPENDIX A

OFFICE OF HUMAN RESEARCH ETHICS
Institutional Review Board

APPLICATION FOR IRB APPROVAL OF
HUMAN SUBJECTS RESEARCH
Version June 25, 2009

Part A.1. Contact Information, Agreements, and Signatures

Date: April 1, 2010

Title of Study: Intimate Partner Violence Prevention Project with the Raleigh/Cary Chinese Community

Name and degrees of Principal Investigator: Huei-Chen Lao, MS, MPH Candidate
Department: Public Health Leadership
Mailing address/CB #: 713417036
Phone #: (919) 541-3418
Fax #: Email Address: lao1@niehs.nih.gov

For trainee-led projects: ___ undergraduate ___ graduate ___ postdoc ___ resident ___ other
Name of faculty advisor: William Williamson
Department: Public Health Leadership
Mailing address/CB #: 4111 McGavran-Greenberg Hall, CB#7469
Phone #: (919) 966-5285
Fax #: Email Address: wwilliam@email.unc.edu

Center, institute, or department in which research is based if other than department(s) listed above: InterAct Family Safety & Empowerment Center (InterAct)

Name of Project Manager or Study Coordinator (if any):
Department:
Mailing address/CB #:
Phone #: Fax #: Email Address:

List all other project personnel including co-investigators, and anyone else who has contact with subjects or identifiable data from subjects. Include name, location (UNC or specific outside location), role and email address for each person who should receive electronic copies of IRB correspondence to PI.
Ritu Kaur, Associate Director of Community Relations, InterAct
rituk@interactofwake.org
Name of funding source or sponsor (please do not abbreviate):

__ not funded  __ Federal  __ State  __ industry  __ foundation  __ UNC-CH
__X__ other (specify): InterAct

For external funding, RAMSeS proposal number (from Office of Sponsored Research):

For industry sponsored research (if applicable):

Sponsor’s master protocol version #:  Version date:
Investigator Brochure version #:  Version date:
Any other details you need documented on IRB approval:

Checklist of Items to Include with Your Submission

Include the following items with your submission, where applicable.

- Check the relevant items below and include one copy of all checked items 1-11 in the order listed.
- Also include two additional collated sets of copies (sorted in the order listed) for items 1-6.

Applications must “stand alone” and should provide all information requested, i.e., complete answers must be contained in the application. While you may reference other documents with supporting information, do not respond solely by stating “see attached.”

Applications will be returned if these instructions are not followed.

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<th>Check</th>
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<tr>
<td>□</td>
<td>1. This application. One copy must have original PI signatures.</td>
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<td>2. Consent and assent forms (include DHHS-approved sample, when one exists), fact or information sheets, phone and verbal consent scripts.</td>
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<td>3. HIPAA authorization addendum to consent form.</td>
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<td>4. All recruitment materials including final copies of printed advertisements, audio/video taped advertisements, scripts, flyers, letters, and emails.</td>
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<td>5. Questionnaires, focus group guides, scripts used to guide phone or in-person interviews, etc.</td>
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<td>6. Documentation of reviews from any other committees (e.g., Clinical and Translational Research Center (CTRC), Oncology Protocol Review Committee, or local review committees in Academic Affairs).</td>
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<td>□</td>
<td>7. Protocol, grant application or proposal supporting this submission, if any (e.g., extramural grant application to NIH or foundation, industry protocol, student proposal). This must be submitted if an external funding source or sponsor is checked on the previous page.</td>
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<td>8. Addendum for Multi-Site Studies where UNC-CH is the Lead Coordinating Center.</td>
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<td>9. Data use agreements (may be required for use of existing data from third parties).</td>
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<td></td>
<td>10. Only for those study personnel <em>not</em> in the online UNC-CH human research ethics training database (<a href="http://cfx3.research.unc.edu/training_comp/">http://cfx3.research.unc.edu/training_comp/</a>): Documentation of required training in human research ethics.</td>
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<td>11. For drug studies, Investigator Brochure if one exists. If none, include package insert for previously approved uses.</td>
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**Principal Investigator:** I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and University policies regarding human subjects research. I will obtain IRB approval before making any changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

_________________________ 
Signature of Principal Investigator 

_________________________ 
Date

**Faculty Advisor if PI is a Student or Trainee Investigator:** I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI.

_________________________ 
Signature of Faculty Advisor 

_________________________ 
Date

Note: The following signature is not required for applications with a student PI.

**Department or Division Chair, Center Director (or counterpart) of PI:** (or Vice-Chair or Chair’s designee if Chair is investigator or otherwise unable to review): I certify that this research is appropriate for this Principal Investigator, that the investigators are qualified to conduct the research, and that there are adequate resources (including financial, support and facilities) available. If my unit has a local review committee for pre-IRB review, this requirement has been satisfied. I support this application, and hereby submit it for further review.

_________________________ 
Signature of Department Chair or designee 

_________________________ 
Date

_________________________ 
Print Name of Department Chair or designee 

_________________________ 
Department
### Part A.2. Summary Checklist  *Are the following involved?*

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<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<tr>
<td>A.2.1. Existing data, research records, patient records, and/or human biological specimens?</td>
<td></td>
<td><em>X</em></td>
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<tr>
<td>A.2.2. Surveys, questionnaires, interviews, or focus groups with subjects?</td>
<td><em>X</em></td>
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<td>A.2.3. Videotaping, audiotaping, filming of subjects, or analysis of existing tapes?</td>
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<td>A.2.4. Do you have <strong>specific plans</strong> to enroll subjects from these vulnerable or select populations:</td>
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<td>a. UNC-CH students or UNC-CH employees?</td>
<td><em>X</em></td>
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<td>b. Non-English-speaking?</td>
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<td>c. Decisionally impaired?</td>
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<td>d. Patients?</td>
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<td>e. Prisoners, others involuntarily detained or incarcerated, or parolees?</td>
<td><em>X</em></td>
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<td>f. Pregnant women?</td>
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<td>g. Minors (less than 18 years)? <em>If yes</em>, give age range: to years</td>
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<td>A.2.5. a. Are sites outside <strong>UNC-CH engaged</strong> in the research?</td>
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<td>b. Is UNC-CH the sponsor or <strong>lead coordinating center</strong> for a multi-site study?</td>
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<td><em>If yes</em>, include the <strong>Addendum for Multi-site Studies</strong>.</td>
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<td><em>If yes</em>, will any of these <strong>sites be outside the United States</strong>?</td>
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<td><em>If yes</em>, is there a local ethics review committee agency with jurisdiction? (provide contact information)</td>
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<td>A.2.6. Will this study use a data and safety monitoring board or committee?</td>
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<td><em>If yes</em>: UNC-CH NC TraCS DSMB? <em>(must apply separately)</em></td>
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<td>Lineberger Cancer Center DSMC?</td>
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<td>Other? <em>Specify</em>:</td>
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<td>A.2.7. a. Are you collecting sensitive information such as sexual behavior, HIV status, recreational drug use, illegal behaviors, child/physical abuse, immigration status, etc?</td>
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<td>b. Do you plan to obtain a federal Certificate of Confidentiality for this study?</td>
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<td>c. Is this research classified (e.g., requires security clearance)?</td>
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<td>A.2.8. a. <strong>Investigational</strong> drugs? (provide IND # )</td>
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<td><em>X</em></td>
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<td>b. Approved drugs for “non-FDA-approved” conditions?</td>
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<td>All studies testing substances in humans must provide a letter of acknowledgement from the UNC Health Care Investigational Drug Service (IDS).</td>
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<td>A.2.9. Placebo(s)?</td>
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<td>A.2.10. <strong>Investigational</strong> devices, instruments, machines, software? (provide IDE # )</td>
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<td>A.2.11. Fetal tissue?</td>
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<td>A.2.12. Genetic studies on subjects’ specimens?</td>
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<td>A.2.13. Storage of subjects’ specimens for future research?</td>
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<td><em>If yes</em>, see instructions for <strong>Consent for Stored Samples</strong>.</td>
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<td>A.2.14. Diagnostic or therapeutic ionizing radiation, or radioactive isotopes, which subjects would not receive otherwise?</td>
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<td><em>If yes</em>, approval by the <strong>UNC-CH Radiation Safety Committee</strong> is required.</td>
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<td>A.2.15. Recombinant DNA or gene transfer to human subjects?</td>
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<td><em>If yes</em>, approval by the <strong>UNC-CH Institutional Biosafety Committee</strong> is required.</td>
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<td>A.2.16. Does this study involve UNC-CH cancer patients?</td>
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<td><em>If yes</em>, submit this application directly to the <strong>Oncology Protocol Review Committee</strong>.</td>
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<td>A.2.17. Will subjects be studied in the Clinical and Translational Research Center (CTRC) or is the CTRC involved in any other way with this study? If yes, obtain the <strong>CTRC Addendum</strong> and submit completed application (IRB application and Addendum) directly to the CTRC. The CTRC includes facilities located on the 3rd floor of the Main Hospital (formerly GCRC) and Ground floor Burnett-Womack (formerly CCCT).</td>
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<td>A.2.18. Will gadolinium be administered as a contrast agent?</td>
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<td>A.2.19. Will subjects’ <strong>Social Security Number</strong> (SSN) be collected for:</td>
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</table>
a. processing payments greater than $200 per year, to support IRS reporting (see also B.6)? __ X_  no
b. processing payments of any amount through UNC-CH Accounts Payable? __ X_  no
c. use as a unique identifier for study tracking purposes for national registry or database? __ X_  no

Part A.3. Conflict of Interest Questions and Certification

The following questions apply to all investigators and study staff engaged in the design, conduct, or reporting results of this project and/or their immediate family members. For these purposes, “family” includes the individual’s spouse and dependent children. “Spouse” includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other’s welfare and shares financial obligations.

A.3.1. Currently or during the term of this research study, does any member of the research team or his/her family member have or expect to have:

(a) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study? __ yes X_ no
(b) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity that owns or has the right to commercialize a product, process or technology studied in this project? __ yes X_ no
(c) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with an entity engaged in the performance of this project as a subcontractor, sub-recipient or vendor? __ yes X_ no
(d) A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process or technology studied in this project? __ yes X_ no

A.3.2. Has the University or has a University-related foundation received a cash or in-kind gift from the sponsor of this study for the use or benefit of any member of the research team? __ yes X_ no

A.3.3. Has the University or has a University-related foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, process or technology studied in this project? __ yes X_ no

If the answer to ANY of the questions above is yes, the affected research team member(s) must complete and submit the form, which is accessible online at http://coi.unc.edu. List name(s) of all research team members for whom any answer to the questions above is yes:

Certification by Principal Investigator: By submitting this IRB application, I (the PI) certify that the information provided above is true and accurate regarding my own circumstances, that I have inquired of every UNC-Chapel Hill employee or trainee who will be engaged in the design, conduct or reporting of results of this project as to the questions set out above, and that I have instructed any such person who has answered “yes” to any of these questions to complete and submit for approval a Conflict of Interest Evaluation Form. I understand that as Principal Investigator I am obligated to ensure that any potential conflicts of interest that exist in relation to my study are reported as required by University policy.
Faculty Advisor if PI is a Student or Trainee Investigator: I accept ultimate responsibility for ensuring that the PI complies with the University’s conflict of interest policies and procedures.

Signature of Faculty Advisor

Date
Part A.4. Questions Common to All Studies

For all questions, if the study involves only secondary data analysis, focus on your proposed design, methods and procedures, and not those of the original study that produced the data you plan to use.

Complete answers must be provided. While you may reference other documents with supporting information, do not respond solely by stating “see attached.”

A.4.1. Brief Summary. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study. Typical summaries are 50-100 words. Please reply to each item below, retaining the subheading labels already in place, so that reviewers can readily identify the content.

Purpose: The Intimate Partner Violence (IPV) Prevention Project with the Raleigh/Cary Chinese is designed to gain qualitative information about the characteristics and risk factors associated with the Intimate Partner Violence (IPV) among the Chinese immigrants who reside in the Raleigh/Cary metropolitan area in North Carolina.

Participants: Female Chinese immigrants who reside in Raleigh/Cary metropolitan area, 18 years of age or older, married or having been in a relationship with a man. Staff members from InterAct, Triangle Area Chinese American Society (TACAS), and Grand Asia Market in Cary.

Procedures (methods): Focus groups with six participants per group will be formed and discussions will be conducted among group members to gain information about their perceptions, opinions, beliefs and attitudes about IPV. Study participant demographics, group discussion records, activity logs, and other records will be kept by investigators for analysis.

A.4.2. Purpose and Rationale. Provide a summary of the background information, state the research question(s), and tell why the study is needed. If a complete rationale and literature review are in an accompanying grant application or other type of proposal, only provide a brief summary here. If there is no proposal, provide a more extensive rationale and literature review, including references.

IPV is a serious social and public health problem which causes physical injuries and psychological harm to the victims. In the United States, IPV was first identified as a national problem four decades ago by feminist movement (Kilpatrick, 2004), and has since gained increasing interest in its intervention and prevention. However, studies on IPV in Asian American population or its ethnic subgroups have been scarce. The purpose of our program is to obtain qualitative, culture-related IPV data from the Chinese immigrants who reside in the Raleigh/Cary metropolitan area in North Carolina. Not only will this information provide us a preliminary description of the nature of IPV in this community, more importantly, it could guide us to form hypotheses and develop programs which will increase the awareness and promote the prevention of IPV among this population.

Focus group discussions will be focused on three themes: (1) Perceptions about IPV—How does each participant perceive and understand IPV as an individual and where does this understanding come from. (2) Influence of specific elements of culture regarding IPV; discuss
the cultural and religious practices, family rituals, gender roles, and the functions of individuals and groups related to IPV. (3) Participants’ awareness and access to agencies that intervene and provide services to IPV victims and survivors, such as Interact.

A.4.3. Subjects. You should describe the subject population even if your study does not involve direct interaction (e.g., existing records). Specify number, gender, ethnicity, race, and age. Specify whether subjects are healthy volunteers or patients. If patients, specify any relevant disease or condition and indicate how potential subjects will be identified. Researchers are reminded that additional approvals may be needed from relevant “gatekeepers” to access subjects (e.g., school principals, facility directors, hospital or healthcare system administrators).

The subject population is female Chinese immigrants who reside in the Raleigh/Cary, North Carolina. The participants will be 18 years of age or older, English-speaking, married or having been in a relationship with a man. We would like to recruit twelve participants and divide them into two focus groups. All participants will be healthy volunteers.

A.4.4. Inclusion/exclusion criteria. List required characteristics of potential subjects, and those that preclude enrollment or involvement of subjects or their data. Justify exclusion of any group, especially by criteria based on gender, ethnicity, race, or age. If pregnant women are excluded, or if women who become pregnant are withdrawn, specific justification must be provided.

We have identified our target population as describes above. Men will be excluded from the study, as the overwhelming burden of partner violence is borne by women at the hands of men. Moreover, our limited resource also necessitates a narrowing of the target population. Only Chinese will be included in this study because the purpose of this study is to obtain qualitative, culture-related IPV data which could guide us to form hypotheses and develop programs that will increase the awareness and promote the prevention of IPV among this population.

A.4.5. Full description of the study design, methods and procedures. Describe the research study. Discuss the study design; study procedures; sequential description of what subjects will be asked to do; assignment of subjects to various arms of the study if applicable; doses; frequency and route of administration of medication and other medical treatment if applicable; how data are to be collected (questionnaire, interview, focus group or specific procedure such as physical examination, venipuncture, etc.). Include information on who will collect data, who will conduct procedures or measurements. Indicate the number and duration of contacts with each subject; outcome measurements; and follow-up procedures. If the study involves medical treatment, distinguish standard care procedures from those that are research. If the study is a clinical trial involving patients as subjects and use of placebo control is involved, provide justification for the use of placebo controls.

Twelve study participants will be divided into two groups. Focus groups in our program will be facilitated by Huei-Chen Lao, under the guidance of Mrs. Ritu Kaur, the Associate Director of Community Relations at Interact of Wake County. Interact is “a private, non-profit, United Way agency that provides safety, support, and awareness to victims and survivors of
domestic violence and rape/sexual assault. Interact also promotes violence-free relationships and communities through collaboration, public information, education and advocacy.” (http://www.interactofwake.org/).

Huei-Chen will prepare questionnaires and have them reviewed by Mrs. Kaur before focus groups start. Questions that are focused on three themes will be presented to the participants to elicit discussion: (1) Perceptions about IPV—How does each participant perceive and understand IPV as an individual and where does this understanding come from. (2) Influence of specific elements of culture regarding IPV; discuss the cultural and religious practices, family rituals, gender roles, and the functions of individuals and groups related to IPV. (3) Participants’ awareness and access to agencies that intervene and provide services to IPV victims and survivors, such as Interact. Responses to the questions will be recorded and collected by Huei-Chen, reviewed and analyzed by her and Ms. Kaur. Huei-Chen is bilingual in Chinese and English and her background of being from the same cultural heritage should help her establish relationship with the focus group participants. In addition, a display for Interact will be set up for the focus groups and it includes the information about the confidential and free services provided by Interact such as 24 hour Crisis-Lines, Youth Education Services, Counseling, Residential Shelter, and Rape prevention Education.

A.4.6. Benefits to subjects and/or society. Describe any potential for direct benefit to individual subjects, as well as the benefit to society based on scientific knowledge to be gained; these should be clearly distinguished. Consider the nature, magnitude, and likelihood of any direct benefit to subjects. If there is no direct benefit to the individual subject, say so here and in the consent form (if there is a consent form). Do not list monetary payment or other compensation as a benefit.

The knowledge gained from this study will provide us a preliminary description of the nature of IPV in this community, more importantly, it could guide us to form hypotheses and develop programs which will increase the awareness and promote the prevention of IPV among this population.

A.4.7. Full description of risks and measures to minimize risks. Include risk of psychosocial harm (e.g., emotional distress, embarrassment, breach of confidentiality), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within the community) and legal jeopardy (e.g., disclosure of illegal activity or negligence), as well as known side effects of study medication, if applicable, and risk of pain and physical injury. Describe what will be done to minimize these risks. Describe procedures for follow-up, when necessary, such as when subjects are found to be in need of medical or psychological referral. If there is no direct interaction with subjects, and risk is limited to breach of confidentiality (e.g., for existing data), state this.

Risk of psychosocial harm to subjects is that subjects may suffer embarrassment if others know that they are the victims of IPV. This factor will be stated in the recruiting letter when we look for study participants. The demographic information that participants provide on the surveys may make them identifiable and vulnerable to retaliations from their partners, therefore all survey evaluations will be anonymous and voluntary. The project database will be accessible only to those individuals with an identification number and password. Identification numbers and
passwords will be given to individuals who work directly on the project and have a clear need to access the data. Also, the database will be located on a secured server.

A.4.8. **Data monitoring and analysis.** Tell how the qualitative and/or quantitative data will be analyzed. Explain how the sample size is sufficient to achieve the study aims. This might include a formal power calculation or explanation of why a small sample is sufficient (e.g., qualitative research, pilot studies). Describe the provisions for monitoring the data to ensure the safety of participants. These plans could range from the investigator monitoring subject data for any safety concerns to a sponsor-based DSMB, depending on the study.

We will produce a focus group summary form as soon as possible after each focus group has taken place. This includes practical details about the time and place, the participants, the duration of the focus group, and details about the content and emerging themes. Data will be collected in the format of transcripts, written answers on an open-ended questionnaire, or notes/memos written by the researcher. The data analysis will be an on-going process for this qualitative pilot study, which means the researcher will think and reflect upon the emerging themes, adapting and changing the methods if required.

Other than analyzing the emerging theme by inductive reasoning (thematic analysis), we will also use comparative analysis which compares and contrasts data from different people until we are satisfied that no new issues are arising. Both analysis methods are often used in qualitative research studies.

A.4.9. **Will you collect or receive any of the following identifiers?** Does not apply to consent forms.

_X_ No  __ Yes  *If yes, check all that apply:*

a. __ Names  
b. __ Telephone numbers  
c. __ Any elements of dates (other than year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death. For ages over 89: all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 and older  
d. __ Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code  
e. __ Fax numbers  
f. __ Electronic mail addresses  
g. __ Social security numbers  
h. __ Medical record numbers  
i. __ Health plan beneficiary numbers  
j. __ Account numbers  
k. __ Certificate/license numbers  
l. __ Vehicle identifiers and serial numbers (VIN), including license plate numbers  
m. __ Device identifiers and serial numbers (e.g., implanted medical device)  
n. __ Web universal resource locators (URLs)
o. __ Internet protocol (IP) address numbers
p. __ Biometric identifiers, including finger and voice prints
q. __ Full face photographic images and any comparable images
r. __ Any other unique identifying number, code, or characteristic, other than dummy identifiers that are not derived from actual identifiers and for which the re-identification key is maintained by the health care provider and not disclosed to the researcher

A.4.10. **Identifiers in research data.** Are the identifiers in A.4.9 above linked or maintained with the research data?

__ yes __X__ no

A.4.11. **Confidentiality of the data.** Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect IDs).

All interview/discussion record will be anonymous and will not have any identifying information connected. All consent forms will be held separately from data collected, therefore disconnecting data from the participants’ names. Hard copy records will be stored in a manner (for example, locked in file cabinets) that limits access to only authorized individuals. Electronic data will be saved on a device that has the appropriate security safeguards such as unique identification of authorized users, password protection, automated operating system patch management, anti-virus controls, firewall configuration, and scheduled and automatic backups to protect against data loss or theft.

A.4.12. **Data sharing.** With whom will identifiable (contains any of the 18 identifiers listed in question A.4.9 above) data be shared outside the immediate research team? For each, explain confidentiality measures. Include data use agreements, if any.

__X__ No one
__ Coordinating Center:
__ Statisticians:
__ Consultants:
__ Other researchers:
__ Registries:
__ Sponsors:
__ External labs for additional testing:
__ Journals:
__ Publicly available dataset:
__ Other:

A.4.13. **Data security for storage and transmission.** Please check all that apply.

*For electronic data stored on a desk top computer:*
_X_ Secure network   _X_ Password access   _X_ Data encryption _X_ Password protected file(s)
__ Other comparable safeguard (describe):

For portable computing devices/external storage devices (e.g. laptop computer, PDA, CDs, memory sticks):
_ _ Power-on password   _ _ Automatic log-off   _ _ Data encryption   _ _ Password protected file(s)
__ Other comparable safeguard (describe):

For hardcopy data (including human biological specimens, CDs, tapes, etc.):
_ X_ Data de-identified by research team (stripped of the 18 identifiers listed in question A.4.9 above)
__ Locked suite or office   _ _ Locked cabinet
__ Data coded by research team with a master list secured and kept separately
__ Other (describe):

### A.4.14. Post-study disposition of identifiable data or human biological materials

Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe your plan to destroy identifiers, if you will do so.

In compliance with “Records Retention and Disposition Schedule, University of North Carolina at Chapel Hill, School of Public Health, Department of Epidemiology” as the schedule for PH Leadership Program (PHLP) is still under development.

Records concerning grant or internally funded research projects by faculty and/or departments/offices including correspondence, project descriptions, final project reports/deliverables, patents or inventions, data, and other related records.

Disposition Instructions:

a. Transfer final project reports/deliverables to the custody of the University Archives 5 years after termination and final payments, when released from all audits, upon approval of the Office of Sponsored Research and after meeting the requirements of the sponsoring agency.

Destroy in office all other related records 5 years after termination and final payments, when released from all audits, upon approval of the Office of Sponsored Research, and meeting the requirements of the sponsoring agency.

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Part A.5. The Consent Process and Consent Documentation (including Waivers)

The standard consent process is for all subjects to sign a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of consent, including signatures, may be altered or waived under certain circumstances.
If you will obtain consent in any manner, complete section A.5.1.

If you are obtaining consent, but requesting a waiver of the requirement for a signed consent document, complete section A.5.2.

If you are requesting a waiver of any or all of the elements of consent, complete section A.5.3.

If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a limited waiver of HIPAA authorization. This is addressed in section B.2.

You may need to complete more than one section. For example, if you are conducting a phone survey with verbal consent, complete sections A.5.1, A.5.2, and possibly A.5.3.

A.5.1. **Describe the process of obtaining informed consent from subjects.**

Describe who will be obtaining consent (or permission) and from whom. Include discussion, as relevant, any waiting period between the initial consent discussion and obtaining consent, and steps that will be taken to minimize coercion or undue influence. If children will be enrolled as subjects, describe the provisions for obtaining parental permission and assent of the child. If decisionally impaired adults are to be enrolled, describe the provision for obtaining surrogate consent from a legally authorized representative (LAR). If non-English speaking people will be enrolled, explain how consent in the native language will be obtained. Address both written translation of the consent and the availability of oral interpretation. It is expected that the information in the consent document(s) will be communicated to participants or their LAR. After you have completed this part A.5.1, if you are not requesting a waiver of any type, you are done with Part A.5.; proceed to Part B.

Preliminary questions and answers sessions will be held among people who are interested in the study and informed consent will be obtained from all of the people who decide to join the focus groups. This includes twelve female Chinese immigrants from the Raleigh/Cary area, 18 years of age or older (therefore no parental permission is required), married or having been in a relationship with a man. For our study, no non-English speaking women will be enrolled due to the limited resources available. Therefore, we will not address the need for interpretation, translations, or LAR services.

A.5.2. **Justification for a waiver of written (i.e., signed) consent.** The default is for subjects to sign a written document that contains all the elements of informed consent. Under limited circumstances, the requirement for a signed consent form may be waived by the IRB if either of the following is true.

**Choose only one:**

a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., study topic is sensitive so that public knowledge of participation could be damaging). Participants should be asked whether they want documentation linking them with the research and the participants’ wishes will govern whether they sign the form. 

   Note: This justification cannot be used in FDA-regulated research.

   __  yes  __  no
b. The research presents no more than minimal risk of harm to subjects and
involves no procedures for which written consent is normally required
outside of the research context (e.g., phone survey).

Explain.

If you checked “yes” to either (and you are not requesting a waiver in
section A.5.3) consent must be obtained orally, by delivering a fact sheet,
through an online consent form, or be incorporated into the survey itself.
Include a copy of the consent script, fact sheet, online consent form, or
incorporated document.

→ If you have justified a waiver of written (signed) consent (A.5.2), you should complete
A.5.3 only if your consent process will not include all the other elements of consent.

A.5.3. Justification for a full or partial waiver of consent. The default is for subjects to give
informed consent. A waiver might be requested for research involving only existing data or
human biological specimens (see also Part C). More rarely, it might be requested when the
research design requires withholding some study details at the outset (e.g., behavioral research
involving deception). In limited circumstances, parental permission may be waived. This
section should also be completed for a waiver of HIPAA authorization if research involves
Protected Health Information (PHI) subject to HIPAA regulation, such as patient records.

__ Requesting waiver of some elements (specify; see SOP 28 on the IRB web site):
__ Requesting waiver of consent entirely

If you check either of the boxes above, answer items a-f.. To justify a full waiver of the
requirement for informed consent, you must be able to answer “yes” (or “not applicable” for
question c) to items a-f. Insert brief explanations that support your answers.

a. Will the research involve no greater than minimal risk to subjects or to their privacy?
   Explain.
   __ yes  __ no

b. Is it true that the waiver will not adversely affect the rights and welfare of subjects? (Consider the right of privacy and possible risk of breach of confidentiality in light of the information you wish to gather.)
   Explain.
   __ yes  __ no

c. When applicable to your study, do you have plans to provide subjects with pertinent information after their participation is over? (e.g., Will you provide details withheld during consent, or tell subjects if you found information with direct clinical relevance? This may be an uncommon scenario.)
   Explain.
   __ yes  __ not applicable

d. Would the research be impracticable without the waiver? (If you checked

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“yes,” explain how the requirement to obtain consent would make the research impracticable, e.g., are most of the subjects lost to follow-up or deceased?). Explain.

e. Is the risk to privacy reasonable in relation to benefits to be gained or the __ yes __ no importance of the knowledge to be gained? Explain.

If you are accessing patient records for this research, you must also be able to answer “yes” to item f to justify a waiver of HIPAA authorization from the subjects.

f. Would the research be impracticable if you could not record (or use) Protected Health Information (PHI)? (If you checked “yes,” explain how not recording or using PHI would make the research impracticable). __ yes __ no Explain.

Part B. Questions for Studies that Involve Direct Interaction with Human Subjects

→ If this does not apply to your study, do not submit this section.

B.1. Methods of recruiting. Describe how and where subjects will be identified and recruited. Indicate who will do the recruiting, and tell how subjects will be contacted. Describe efforts to ensure equal access to participation among women and minorities. Describe how you will protect the privacy of potential subjects during recruitment. For prospective subjects whose status (e.g., as patient or client), condition, or contact information is not publicly available (e.g., from a phone book or public web site), the initial contact should be made with legitimate knowledge of the subjects’ circumstances. Ideally, the individual with such knowledge should seek prospective subjects’ permission to release names to the PI for recruitment. Alternatively, the knowledgeable individual could provide information about the study, including contact information for the investigator, so that interested prospective subjects can contact the investigator. Provide the IRB with a copy of any document or script that will be used to obtain the patients’ permission for release of names or to introduce the study. Check with the IRB for further guidance.

Investigators will collaborate with the Triangle Area Chinese American Society (TACAS) to recruit the subjects. TACAS is dedicated to community services and co-organizes various local events such as Asian American Health Fair and immigration seminars. We will distribute flyers during TACAS events; advertise on the TACAS Newsletter and website. We will also give pamphlets and flyers at Grand Asia Market which is located at Cary and is visited by numerous Chinese in the area.

Questions and answers sessions will be held for interested people and they will be invited to the study. However, they will become study participants only after they sign the written consent.

B.2. Protected Health Information (PHI). If you need to access Protected Health Information (PHI) to identify potential subjects who will then be contacted, you will need a limited waiver of HIPAA authorization. If this applies to your study, please provide the following information and complete Section C.
a. Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects. What information are you planning to collect for this purpose?

b. How will confidentiality/privacy be protected prior to ascertaining desire to participate?

c. When and how will you destroy the contact information if an individual declines participation?

B.3. **Duration of entire study and duration of an individual subject’s participation, including follow-up evaluation if applicable.** Include the number of required contacts and approximate duration of each contact.

The duration of the whole study is one month and two meetings will be held for each focus group. The first meeting will last 60 minutes; the second meeting will last 45 minutes followed by a 15 minute post-class evaluation survey.

B.4. **Where will the subjects be studied?** Describe locations where subjects will be studied, both on and off the UNC-CH campus.

All meetings will be held at InterAct Family Safety & Empowerment Center, 1012 Oberline Road, Raleigh, NC 27605

B.5. **Privacy.** Describe procedures that will ensure privacy of the subjects in this study. Examples include the setting for interviews, phone conversations, or physical examinations; communication methods or mailed materials (e.g., mailings should not indicate disease status or focus of study on the envelope).

Subjects will be assigned a coded number when they sign up on a class roster or when they complete a survey for the program. Therefore, only the demographics associated with the subject, not their name, will be used for data analysis. All documents containing name and contact information of the participants will be kept in a locked cabinet that will be accessible only to the principal investigator (Huei-Chen Lao) and Ms. Kaur. Information will then be entered into a database by the principal investigator which will be password protected. This will also be only accessible to the principal investigator and Ms. Kaur. No program materials will be mailed to the home of program subjects.

B.6. **Inducements for participation.** Describe all inducements to participate, monetary or non-monetary. If monetary, specify the amount and schedule for payments and if/how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completing it. For compensation in foreign currency, provide a US$ equivalent. Provide evidence that the amount is not coercive (e.g., describe purchasing power for foreign countries). Be aware that payment over a certain amount may require the collection of the subjects’ Social Security Numbers. If a subject is paid more than $200.00 per year, collection of subjects’ Social Security Number is required (University policy—see SSN Guidance) using the Social Security Number collection consent addendum found under forms on the IRB website (look for Study Subject Reimbursement Form).
No monetary inducement will be provided. A reception will be held after the second meeting and each participant will be given a bag of gifts which is valued no more than $10.00.

B.7. **Costs to be borne by subjects.** Include child care, travel, parking, clinic fees, diagnostic and laboratory studies, drugs, devices, all professional fees, etc. If there are no costs to subjects other than their time to participate, indicate this.

Costs to the program participants will be kept to a minimum. Costs incurred to participants include their time and some travel expenses to InterAct which is centrally located in Raleigh. Child care services during the group sessions will be provided by InterAct staff members.
References


http://www.census.gov/
