IRB Office Use ONLY
IRB number _____
Date submitted_____
Initials _____
FB_____ Expedited _____

Boston University
CRC Non-Exempt IRB Application

*****This application is intended to be used for submission of research that does NOT qualify for Exempt review. If your research qualifies for Exempt review please complete the BU CRC Exempt Application posted on the IRB website www.bu.edu/irb. If you are not sure whether or not your study qualifies for Exempt review please consult the information on the website under "Exempt Review". Completing the incorrect application can result in a delay in IRB review.**

Section A: Title and Investigators

A.1. Main Study Title (spell out acronyms)

Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study

A.2. Principal Investigator

Name: Hyeouk Chris Hahm
Title: Associate Professor
School / Department: Boston University School of Social Work
Mailing Address: 264 Bay State Rd. Boston, MA 02215
Email Address (Required): hahm@bu.edu
Name of Administrative Contact (*if applicable):* Melissa Alexander
Email for Admin Contact: melissa.alexander@post.harvard.edu
Telephone Number for Admin Contact: (617) 353-3925

PI must provide documentation of human subjects protection training. For more information see IRB website www.bu.edu/irb. Please include documentation of the training with this Application.

I confirm that **all** those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms and training as dictated at http://www.bu.edu/orc/coi/forms/, and as provided under the Boston University Policy on Investigator's Conflicts of Interest.
X YES (Required)

Of the financial interest disclosure forms submitted, has anyone checked "yes" to any of the questions on either the FIND1 or NONFIND1 form?

____ Yes* **X** No

***If anyone checked "yes" to any of the questions on either the FIND1 or NONFIND1 form, the IRB Director will contact the COI office to obtain the disclosure information.**

PI status :
BU faculty X **BU student**: ___ **doctoral** ____**masters** ___**other (specify)** _____

If student: n/a
Name of faculty advisor: n/a
Email address (REQUIRED): n/a

If the PI is a student then the faculty advisor must be listed as a co-investigator on the protocol (below), and the faculty advisor must sign off on the IRB protocol (at the end of this application). For more information about Student Research consult the IRB website www.bu.edu/irb under "Guidance for Students Conducting Research".

A3 : Co-investigators- Boston University personnel

In this section list ALL **BU persons** who will be conducting research activities or will be engaged in the research. (This section is for **BU personnel only**. For non-BU faculty/staff/students go to Section A4) For the purpose of this application co-investigators include all persons who will have contact with subjects or their identifiable data and those who will perform research activities including recruitment, enrollment, consenting subjects, collecting data, performing study interventions, analyzing data, conducting focus groups, performing long-term follow-up. **Copy and paste and then complete the box below for each co-investigator.**

Name of BU co-investigator :
School/ Department
Telephone Number
Email address (REQUIRED)

This person must provide documentation of human subjects protection training. For more information see IRB website www.bu.edu/irb.

Is this person ___BU faculty/staff ___BU student ___Other *(specify)*

A.4. Non-BU co-investigators

***Important note: Ordinarily BU IRB review only applies to BU faculty or staff. If investigators from other institutions are engaged in the research then, in many instances, IRB review must also be conducted at the other institutions and those investigators should not be listed on the BU IRB application. In some instances, BU may consider conducting IRB review for investigators from another institution. If this is the case then there needs to be an IRB Authorization Agreement and then those investigators must be listed in this section. The IRB determines whether it will enter into Authorization Agreements on a case by case basis. For more information about this please see the IRB website www.bu.edu/irb under "Conducting research with other institutions". If your research involves "investigators" who are not affiliated with another institution then please contact the IRB office for more information.

___ Check here if all research activities will be conducted ONLY by BU investigators at BU sites

X Check here if portions of the research will be conducted by investigators from another institution but the other institution(s) will also be conducting IRB review(s). *If BU is the primary awardee of the grant then you must provide proof of IRB approval or verify that you will be obtaining proof of IRB approval from all of the other sites.*

____ Check here if portions of the research will be conducted by investigators from another institution and you are requesting an IRB Authorization Agreement with the other institution.

Complete the following information in the box below for EACH non-BU investigators. If unsure, please check with IRB office to verify whether the non-BU investigators need to be listed on this application before proceeding. Copy this box and complete for each non-BU investigator.

Name of non-BU co-investigator: Denise Hien (Ph.D)

Institution or company affiliation: Research Foundation for Mental Hygiene/ NY State Psychiatric Institute, City College of CUNY
Telephone Number: dhien@ccny.cuny.edu
Email address (REQUIRED): dhien@ccny.cuny.edu

This person must provide documentation of human subjects protection training. For more information see IRB website www.bu.edu/irb.

This person may need to complete a BU Project Specific Disclosure (PSD) for Conflict of Interest or may need to follow his/her own institution's policy regarding COI. Consult with OSP for details.
___ check here if OSP has indicated that a BU PSD is NOT required
X check here if OSP has indicated that a BU PSD is required – and if so that it is attached to this application.

Did this person have a potential COI on the PSD? ____ Yes **X** No

Is this person **X** faculty/staff ___student ___ Community person
____Other *(specify)*

A.5. Funding

Provide in this section information regarding ALL SOURCES of funding. **This includes any pending funding or funding that has been applied for to support** this research. Note: the IRB cannot complete IRB review without also reviewing the grant or sponsor's protocol with the IRB application. Note: Federal regulations REQUIRES IRB review of the grant as part of the IRB review of the protocol.

(Check all that apply):

X BU is/will be the primary awardee of the grant. A copy of the grant application (face page, abstract, research plan, specific aims, background and significance, preliminary studies, research design and methods, human subjects and all appendices that relate to study conduct such as survey instruments, data collection forms, etc.) must be attached.

___ BU is/will be a sub-award. (Instead of the entire grant application, only a copy of the sub-award agreement must be attached.)

___ This is/will be industry sponsored/foundation sponsored research. A copy of the full sponsor's protocol must be attached.

(Check all that apply)
___ Unfunded research
___ Departmentally funded
___ Industry funded
X Government funded
___ Foundation funded /other (specify**)** _____

For each source of funding or potential funding provide the following information
Sponsor's name National Institute of Health: (decision pending)
Award number/ Source Number: (decision pending)
PI of award: Hyeouk Chris Hahm
Comments ***(if applicable)***

X check here if you have received JIT notification or NoA (notification of award) or notification from the funding source that you have received a "fundable score"
___ check here if this is an ARRA award

A. 6. International Research **X** N/A

___ Check here if this study involves international research (research conducted outside the US)
___ Check here if this study has been reviewed or will be reviewed by one or more international IRBs/ethics boards

A.6.a. List all the countries non-US countries where research will take place and specify any non-US IRBs that will be reviewing the research

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Section B IRB Review Path Determination

IRB Review process- If you are submitting a protocol for Exempt review or a Not Human Subjects Research determination STOP HERE. Instead go to the IRB website www.bu.edu/irb and download the CRC Exempt application. If you are not sure whether your study qualifies for Exempt review, consult the power point slides on the IRB website or contact the IRB office at 617-358-6115 for more information. Completing the wrong form can result in a delay in processing your application.

B.1. Federal Regulations require review by the Full IRB at a convened meeting if the study is greater than minimal risk or if all the study activities do not fit into one of the Expedited Categories. Please provide the following information to help the IRB ascertain during pre-

review if the study will require full board review. **Note: the final determination as to whether a study requires IRB review is made by the IRB.**

(Check all that apply)

___ This study involves administration of drugs (including FDA approved drugs and over-the-counter drugs as part of the research. *(Full board (FB)review required)*

___ This study involves an investigational medical device or an approved medical device used in an investigational manner. *(FB review required)*

___ This study involves the collection of blood (greater than 50 cc from adults) or spinal fluid by lumbar puncture or any other biopsies or invasive tissue collection. (Will usually require *FB review)*

___ This study involves administration of x-rays, dexa-scans or other ionizing radiation as part of the research. *(FB review required)*

X This study involves the collection of information from subjects for research purposes that is sensitive and if disclosed could put subjects at risk for legal or social harms (i.e. use of illegal drugs, HIV status, psychiatric illness, sensitive information related to sexual behaviors, etc.)

X Research includes collection of information that might indicate subjects might harm themselves or others (i.e. collection of data about child abuse, elder abuse, suicidality).

X Research activities include focus groups.

___ Research involves collection of samples or data for genetic analysis or for placement in a research repository or registry.

Section C: Study Summary

In the box below provide a brief (no more than 300 words) summary in LAY terms.

Our objective is to systematically modify the existing evidence-based intervention, "Seeking Safety" (SS), by integrating a gender-specific HIV intervention (Project FIO) and critical cultural components for Asian-Pacific Islander (API) women with a history of violent traumatic experience or a diagnosis of Post-Traumatic Stress Disorder (PTSD). This is significant because it aims to reduce two public health problems among API women: 1) rising incidence of HIV/STIs, and 2) the highest rates of completed suicide between the ages 15 to 24 among all racial groups of women. We will develop new protocols which incorporate SS, Project FIO, API women's unique experiences, and feedback from an API Community Advisory Board. Feasibility and safety will be tested through a pilot randomized clinical trial (RCT). We will launch the Asian Women's Action for Resilience and Empowerment

(AWARE): A Stage IA and IB Intervention Development Study to screen at least 400 women in the greater Boston area and recruit a total of 96 women who meet the criteria for PTSD and traumatic history. The 8-week intervention will be given group psychotherapy along with secure mobile messages. Adherence to group psychotherapy, utilization/satisfaction of text messages, and safety (suicidality and intimate partner violence) will be tested as feasibility outcomes. The efficacy will also be tested by measuring HIV-related outcomes and psychiatric symptoms and substance use at baseline, week 8, and 3 months to determine effect of the adapted intervention. There will be a Focus Group Feedback Discussion after the 8-week psychotherapy sessions to allow participants to comment on the effectiveness of the intervention. This integrative approach is innovative in multiple ways: (1) the study will be the first pilot RCT study to target traumatized API women, (2) it feasibly incorporates a culturally appropriate intervention, (3) it is designed to reduce HIV risk behavior, and (4) it tests the feasibility of mobile technology. It is our aim that these efforts will ultimately lead to the reduction of HIV transmission, suicidality, and psychiatric symptoms among API women.

Section D: Background/ Rationale/ Purpose

In the text box below provide the following study information

- Background information
- Study rationale
- Study objectives and/or hypotheses

Background information: The proposed 3-year adaptation and pilot testing of the Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study consists of the following goals: (1) provide the original Seeking Safety (SS) [1] curriculum to Asian Women Discussion Group members for feedback and revision; (2) fully develop the AWARE protocol (which will modify SS by integrating Project FIO[2] and our cultural component) for API women; (3) use a pilot two-armed RCT design to test the feasibility and safety of our adapted intervention in Year 2, comparing the AWARE intervention group (n=48) with the wait-list group (n =48); and (4) employ multiple measures of the same constructs using a repeated measures design (assessments at pre-test, 8 weeks, and 3-month follow-up). We chose an RCT design to (1) establish the validity of statistical testing to the maximum level and (2) minimize potential biases (known and unknown factors and characteristics of the intervention and control groups). We will obtain outcomes for feasibility, safety, and preliminary efficacy of the primary outcomes (HIV-related outcomes) and secondary outcomes (psychiatric symptoms, substance use). These feasibility, safety, and efficacy outcomes will allow us to better plan for a larger-powered study. We will conduct the focus groups and pilot RCT at Boston University, School of Social Work (BUSSW), MA.

Study rationale and significance: *There is a mental and sexual health crisis in the API community in the US, particularly among young women (ages 18-35). This proposed*

project is intended to deepen our national understanding of this crisis and move us toward highly innovative solutions. We propose to design an appropriate intervention that reduces mental and sexual health problems in this population. There are 3 significant reasons why this study should be funded for research:

1. Lack of available preventive methods and research despite rising incidence of STIs and HIV/AIDS in API women. There is growing evidence that demonstrates a rapid increase in the incidence and prevalence of sexually transmitted infections (STIs) and HIV among APIs.[6] Although APIs have the lowest overall prevalence of HIV, accounting for 1% of reported cases, the API population had the highest percentage increase in HIV between 2004 and 2007 (44%), compared to Blacks (11%), Hispanics (21%), and Whites (16%)[6]. No randomized clinical trials focusing on API women's sexual health exist, and only one study exists on API adolescent girls' substance use prevention programs, highlighting the dearth of research on API women in clinical trials.[24]

2. The intersection between poor mental health, substance use, and trauma. In addition to HIV/STIs, API women are at high risk for suicidal ideation and behaviors. For API women aged 15-24, suicide was the second leading cause of death behind accidental injury between 1999-2007, whereas it is third for Whites, and sixth for Blacks.[7] Asian American college students were 1.6 times more likely to attempt suicide compared to their White counterparts in 1999-2000.[25,26] In a recent study, young API individuals showed a higher prevalence of suicidal ideation and suicidal attempts than older API individuals.[27] Moreover, young API women showed greater risk than young API men.[28] Our previous study identified through logistic regression models that while not all types of drug use are associated with suicidal ideation and suicide attempts, having a history of hard drug use alone or in combination with soft drug use had a statistically significant association with both suicidal ideation (OR = 3.0, CI: 1.6-5.6) and suicide attempts (OR = 4.3, CI: 1.8-9.8), even after adjusting for demographic covariates. [29] This strong link between suicidality and substance use may be a result of self-medicating behavior in which an individual attempts to manage or avoid distressing symptoms to relieve painful emotions.[30]

3. Low reporting rates and under-utilization of treatment for traumatized API women. API women who were victims of sexual assault are particularly vulnerable. API women may experience higher levels of psychological distress or have fewer adaptive coping skills/social supports compared to sexually-victimized White women.[33] *Rau and Diclemente found that API parents of sexual victims provide less support and minimal involvement in helping victims to seek evaluation and treatment with the appropriate services.*[37] Our AWSHIP study showed that the experience of child sexual abuse combined with other types of abuse was the most powerful and robust predictor of severe depression, suicidal ideation, and suicide attempts.[26]

Study objectives and/or hypotheses: The aim for *year one* is to adapt an intervention for API women that reduces HIV risk behaviors while increasing HIV knowledge and self-efficacy in negotiating safer sex (primary outcomes) and reduces psychiatric symptom severity and substance use (secondary outcomes). During *year 2*, the feasibility and safety of stage 1B of the AWARE intervention will be established through a pilot RCT, in which an intervention group will receive AWARE (n=48), which will have adapted SS by integrating Project FIO and

cultural components. During *years 2 and 3*, the preliminary efficacy of the intervention for API women will be tested.

It is hypothesized that the AWARE intervention group will significantly exceed the wait-list group in reduction of HIV risk behaviors and increased HIV knowledge and self-efficacy in negotiating safer sex at the 8 weeks and 3 months post-test points (primary outcomes). Additionally, the AWARE intervention group will significantly exceed the wait-list group in reduction of PTSD symptoms (and/or other mental health outcomes) and the frequency of substance use (at 8 weeks and 3 months post-test) (secondary outcomes).

Section E: Study subjects

E. 1. Gender

Select gender of subjects: ___male **X** female ___both

E. 2. Age

Age range of subjects: (check all categories that apply to any of the subjects)

X Adults (18 years and older)
___ Infants (< 1 year)
___ Young children (1-6 years of age)
___ Children 7-11 years
___ Adolescents (12-17 years of age)

E. 3. Race/ Ethnicity (check all that apply)

____ Mixed race or ethnicity
____ American Indian or Alaskan Native
X Asian or Pacific Islander
____ Black (not of Hispanic Origin)
____ Hispanic
____ White (not of Hispanic Origin)
____ Not available – race/ethnicity data will not be collected as part of this study (Note: collection of race/ethnicity data is required for some federally funded research. Consult the sponsor for details.)

E. 4. Language

Federal regulations require that consent be given in a language understandable to the subject In most cases consent documents will need to be translated into the subjects' languages. ***Note that if informed consent is required, translation of documents will be required. Translation "on the fly" by a translator from English to another language is not allowed. **Non-English versions of consent documents must be approved by the IRB prior to use**. ***Do not translate consent documents until IRB approval has been obtained for the English version. Please see the IRB website www.bu.edu/irb for information about translation and attestation requirements.

E.4. a. List all languages in which you intend to obtain informed consent.

English

E. 5. Vulnerable Populations

E.5. A. Indicate all vulnerable populations who will be recruited as subjects and/or about whom study data will be obtained

X BU students
___ BU employees /faculty/ lab personnel
___ Minors (children under 18 years of age)
___ Cognitively or decisionally impaired
X Mentally ill/ psychiatric patients
___ Homeless
X Pregnant women
___ Pregnant minors
___ Fetuses
___ Prisoners or incarcerated persons including parolees
___ Adult wards of the state
___ Child wards of the state

E. 5. B. Special Protections

Vulnerable populations require special protections. Explain the measures that you will take to obtain informed consent, protect confidentiality and prevent undue coercion in all of the above populations that you have selected.

E.5.B Special protections to vulnerable populations

The Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study has proposed to include individuals who may be mentally ill or be a psychiatric patient in all 3 of our participant groups: the Asian Women Discussion Group , AWARE intervention group, and wait-list group. While working with these individuals we will make the following special provisions to insure safety for this vulnerable population.

Secure Mobile Messaging: We will emphasize that for this pilot study, the secure messaging system (CoverMe) is not meant to be interactive; rather, it summarizes each session's themes and shares the real-world stories of API women, and the system will inform us when the participants read the messages. However, in the event that participants reply to us with strong emotions or comments, we will respond to them in a sensible and appropriate way as soon as we receive text message replies.

We have prepared the following 20 plausible scenarios and responses in the event that participants send us text messages in regard to mental health status, traumatic events, substance use, and suicidality:

1. "I'm feeling really depressed right now."

Response: That is a very strong emotion to have. The therapist will contact and schedule a meeting with you this week to determine if other forms of treatment or a referral might be beneficial to you.

2. "This quote reminds me of when I was sexually abused." Response: These quotes are very powerful and often illicit personal responses and feelings. It may be beneficial for you to address your responses in the next session and inform the therapist of how you are feeling.

3. "This quote reminds me of when I was physically abused."
Response: These quotes are very powerful and often illicit personal responses and feelings. It may be beneficial for you to address your responses in the next session and inform the therapist of how you are feeling.

4. "I want to cut myself."
Response: We recognize that you have been through many challenging experiences. Dr. Hyeouk Hahm will contact you shortly by phone to provide support.

5. "I'm feeling suicidal lately; I don't know what to do."
Response: We recognize that the sessions may be evoking certain feelings and memories. We encourage you to call your local Psychiatric Emergency Service (PES). Dr. Hyeouk Hahm will contact you immediately by phone to provide support.

6. "I'm feeling really hopeless right now…what's the point? There's nothing to live for—I should just end it now." Response: It is apparent that you are having a difficult time right now and have thoughts of wanting to hurt yourself. We encourage you to call the local ER. Dr. Hyeouk Hahm will contact you immediately for support.

7. "This quote reminds me of a destructive relationship I've had." Response: These quotes are very powerful and often elicit memories. It may be helpful to share your response in the next group session.

8. "I can really relate to this quote. I've never felt like I was good enough or valued by anyone."
Response: These quotes can often evoke certain feelings and memories from one's personal experiences. It may be helpful for you to share and reflect on this in the next group session.

9. "I can really relate to this quote—as a child I was taught to conceal my emotions. It's very hard for me to show/tell people how I really feel." Response: It seems like you really identify with this quote. This is something that we encourage you to share and reflect on in the next group session.

10. "This is very hard for me…I'm not sure if I'm going to return to the sessions." Response: We understand how the sessions may be difficult or bring back a lot of memories. However, we think it would be best for you to contact the therapist first to discuss what these sessions are bringing up for you and any concerns you may have.

11. "This quote reminds me of what happened to me. I am always having flashbacks, intrusive thoughts, and sometimes feel like I'm reliving the experience."
Response: It seems like the event you have experienced is currently impacting you in many ways. It is imperative that you tell the therapist what you are experiencing over the phone or at the next session.

12. "This quote reminds me of my current relationship: my partner is violent towards me."
Response: It may be beneficial for you to sit down with the therapist prior to the next session. One of our team members will call you to talk further.

13. "I've been having a really bad week…I think my depression has gotten worse." Response: We think it's important and encourage you to inform us of how you are feeling throughout the study. The therapist will call you within the next few days to set up an appointment to talk further.

14. "Lately, I've been drinking a lot to just cope with everything. I don't know how else to deal with my problems, but I know it's got to stop." Response: We commend you for addressing and acknowledging what has been going on. Please share these feelings with the group next session.

15. "I feel as if my family and friends aren't able to understand what I went through." Response: We commend you for attending and participating in the group sessions. It may be beneficial to share your feelings with the group next session.

16. "I can relate to this quote; I used to have similar responses. I used to find pleasure in harming myself. I used to cut myself for a long time." Response: Thank you for sharing your experience. It is possible that many other group members have had similar experiences. It may be useful to you and the group to share your story.

17. "I just don't feel worthy as person, no one is ever going to love me or care about me."
Response: We recognize that these are strong emotions. If you feel comfortable, we recommend that you share these thoughts with the group. The therapist will call you this week to check in.

18. "I can really relate to that—I have trouble setting boundaries in relationships…People walk all over me; I'm weak." Response: We think you are a very strong person for openly talking about your feelings and emotions. We encourage you to share your response with the group next session.

19. "The sessions are becoming very stressful for me; I find myself feeling upset when I leave."
Response: Thank you for sharing this. We want to do whatever we can to make this a more positive experience. The therapist will call you this week to check in.

20. "I can relate to this quote, I don't know what's to become of my future…I am a complete failure."
Response: Thinking about the future can evoke uncertain feelings. Others may be experiencing similar feelings; it may be valuable for you to address these concerns in the session.

<u>Adverse Events</u>

This study carries some risk for the development of suicidal ideation, suicide attempts, and self-mutilation as adverse events because the women eligible to participate have PTSD or a history of violent trauma. In order to address this risk, we will evaluate potential development of these adverse events at baseline, 8 weeks, and the 3-month follow-up, as well as informally monitoring participant condition on a weekly basis. Participants in the wait-list group will also be assessed for adverse events over the phone at 3 weeks and 6 weeks after the start of treatment for the intervention group. Participants will also be asked to keep a Weekly Adverse Event Log to

measure safety outcomes. In addition, since our screening measures may detect suicidal risk and intimate partner violence, we will also provide appropriate care as necessary. We will use the following assessments to assess risk:

a. Self-mutilation: We will assess self-mutilation using the Columbia-Suicide Severity Rating Scale (C-SSRS). The C-SSRS is a scale administered by a trained individual to assess past suicide attempts and severity of suicidality. Questions address suicidal ideation, intensity of ideation, non-suicidal self-injury, and actual suicide attempts. Questions have either yes/no answers or answer choices scored on a severity of 1-5. The scale exhibits a moderate to high internal consistency, with Cronbach's alpha of 0.7, 0.7, and 0.9, respectively for three existing studies.

b. Suicidality: We will also assess suicidality using the C-SSRS (see item a, above).

c. Intimate Partner Violence (IPV): We will assess IPV using the Revised Conflict Tactics Scale (CTS2). The CTS2 is a self-administered questionnaire which measures the extent of partner conflict and negotiation tactics used. A scale of 0 to 7 to rate 78 relationship behaviors based on frequency. The items belong to the following categories: Negotiation, Psychological Aggression, Physical Assault, Sexual Coercion, and Injury. Cronbach's alpha coefficients range from 0.86- 0.95. Those who meet the criteria severe IPV will be excluded. Women who report 1 or higher (i.e., "My partner did this to me one or more times") for any items in the "Severe" subscale of the Physical Assault, Sexual Coercion, and Injury scales will be excluded from the study (these items are bolded and highlighted on the CTS2, enclosed). Examples of "severe" items include "My partner slammed me against a wall" and "My partner beat me up." We will provide appropriate referral sources for additional preventive and clinical services for women who meet criteria for severe IPV at any time during the intervention.

If a participant is determined to be at serious risk for suicidal ideation, suicide attempts, self-mutilation, or severe IPV at any assessment point (clinical screening, baseline, 8 weeks, and 3-month follow-up), or through the Adverse Event Log, weekly contact, wait-list group follow-up (at 3 weeks and 6 weeks after randomization), or text messaging, the therapist will call Dr. Hahm immediately by telephone. Dr. Hahm will then call the participant and immediately and assess suicide risk. If risk is determined to be present, the following protocol will be implemented depending on level of risk:

(1) Mild risk (e.g. suicidal ideation present without presence of current plan, low intent, presence of hope, no current means).

a. The participant will be encouraged to call the local Psychiatric Emergency Service (PES).

b. She will also be encouraged to discuss her feelings with family members or close friends.

c. Follow-up contact will be provided by the therapist until risk is determined to be minimal.

(2) Moderate risk (e.g. suicidal ideation present with additional risk factors: moderate intent, low hope, possible plan and/or possible means).

a. The participant will be encouraged to call the local Psychiatric Emergency Service (PES).

b. If the participant refuses to call PES, we will enlist the assistance of a family member, roommate, or close friend to do so.

c. If the participant refuses to enlist family, friends, or a roommate, or if they are not present, she will be encouraged to have the therapist call for her. Should the participant refuse, and if no one is in the home to ensure ongoing safety, the therapist will make the phone call against her will.

d. A plan for removing from the home any means with which to commit suicide, preferably with the assistance of family or trusted other, will be developed.

e. There will be continuous follow-up phone contact (with the therapist or Dr. Hahm) ensuring the participant's safety throughout the day and then on a daily basis until risk is determined to be mild. Phone calls will then occur less frequently until risk is determined to be minimal. The participant will be told at the outset of participation that, if suicide risk is present and they cannot be reached by phone, the local safety authority or police will be called.

(3) High risk (e.g. suicidal ideation present with several additional risk factors: high intent, no hope, a definite plan, and current means).

a. The participant will be encouraged to call the local emergency room (ER).

b. If the participant refuses to call the local ER, she will be encouraged to allow the PI or therapist to make the ER call. Should the participant refuse, the therapist or PI will make the phone call against her will. They will send an ambulance or unit to the home.

Section F: Study Design and Procedures

F.1. Study Design (check all that apply)

X Randomized trial
___ Non-randomized trial testing new or experimental procedures or interventions
___ Survey, interview
X Focus groups
___ Database review, record review
___ Epidemiological research
___ Secondary analysis of previously collected data
___ Other (specify):

F. Eligibility Criteria

F.2. Inclusion criteria (either the inclusion criteria for subjects or criteria for selection of records to review**)** Indicate if you have different inclusion criteria for different study cohorts

Demographic criteria. In order to be ensure eligibility for the initial screening and assessment, we will ask potential participants the following questions:

(1) How or where did you hear about our study? Why did our advertisement grab your attention/our outreach effort interest you?
(2) What is your sex (should be female only)?
(3) What is your age as of today (should be between 18 – 35)?
(4) What racial and ethnic do you identify with (should Chinese, Korean, or Vietnamese)?
(5) In what country were your mother and father born?
(6) What languages are you fluent in reading, writing, and speaking?
(7) Are you currently or have you ever been sexually active?
(8) Do you currently have a mobile phone (either a regular phone or a smart phone) with a text-messaging plan?

Both pregnant and non-pregnant women may participate. We will also include those who are already in other types of psychotherapy, as exampled by previous studies that have used SS. There are no inclusion or exclusion criteria based on HIV status, which will not be collected as part of this study

If all answers to the above 8 questions meet the criteria, a participant will be invited to come to BUSSW to answer screening and assessment questions. Before completing the screening/assessment the study will be fully explained, presented orally and in writing, and participants will be asked to sign a statement of informed consent. Potential participants will be told that there are two phases of the project: the Asian Women Discussion Group (Stage IA of the program) and Stage IB of the program (randomized clinical trial). Individuals who are eligible may be selected for Asian Women Discussion Group may not participate in the second stage of the program. *Clinical criteria for selection* Asian Women Discussion Group *or Stage IB participation.* In addition to meeting all demographic criteria, these women must also:

(1) meet the threshold of a traumatic life event (As determined by the Traumatic Life Events Questionnaire to assess lifetime trauma history and be used to determine if a participant has ever undergone an event that qualifies as a traumatic stressor according to DSM-IV criteria)
or
(2) have a current diagnosis of PTSD (As determined by the Clinical Administered PTSD Scale to diagnose PTSD resulting from trauma that occurred in the past 30 days; this structured interview measures the symptoms of PTSD corresponding to DSM–IV criteria)

Women who meet the threshold criteria will be invited to participate in the first step of the study: participation in the Asian Women Discussion group, which consists of 10 psychotherapy sessions and an additional post-intervention meeting. This focus group will provide crucial feedback to help refine the sessions. Because only ten women who meet the eligibility guidelines will be selected: most women will not be selected.

F.3. Exclusion criteria (Indicate if you have different exclusion criteria for different cohorts)

Exclusion criteria. Women who meet any of the following criteria will be ineligible for the study:

(1) Significant current risk of homicidal or suicidal behavior (deliberate self-injury where there is at least some admitted or inferred intention to die; particularly, participants who have had a suicide attempt within the past year or participants with active suicidal ideation with intent or plan)
(2) Presence of schizophrenia, schizoaffective, or organic mental disorders using DSM-IV criteria
(3) Women of mixed race (i.e., those who do not identify as 100% Chinese, Korean, or Vietnamese or a mixture thereof)
(4) Victims who have experienced natural disasters or other non-violent trauma only (i.e., those who have not been traumatized by physical or sexual violence)
(5) Women who are currently victims of severe Intimate Partner Violence (IPV) using The Revised Conflict Tactics Scale (CTS2).
(6) Women who experience worse outcomes than baseline two weeks after the study begins will be withdrawn from the study.

Justification for Exclusion Criteria: We aim to create a homogeneous sample with regard to heterosexual female victims of violent trauma. The reason for excluding victims of non-violent trauma is because studies have found that assaultive violence is more likely to lead to PTSD and that victims of assault exhibit more elevated PTSD symptoms compared to victims of non-violent trauma or natural disasters. We specifically include 1.5 and 2nd generation children of immigrants due to the elevated health risks and various stressors that are acculturation-related. We expect that approximately 10 % of the subjects experience current IPV based on the epidemiological data on IPV among API women indicating 1.6 % of API women reported severe IPV vs. 9.2 % experiencing less severe types of IPV. We have decided to exclude severe types of IPV because of our concern that participation in intervention among those who reported severe current IPV may increase risk of IPV although Melendez et al. has shown that there was no increase in IPV among those who completed 8 weekly sessions of Project FIO.

F.4. Study procedures

In the box below provide a detailed description of the study including **all the procedures to be performed** (preferably in sequential order). Be sure to specify which procedures are experimental (i.e. testing a new intervention for psychiatric illness) versus which procedures are standard of care. Be sure to include the following information:

- Methods of data collection
- Details regarding experimental interventions
- Number, frequency and duration and types of subject contacts (visits, phone calls, internet surveys, mailings, etc.)
- Duration of participation for single subject
- Anticipated duration of the entire study (up to and including data analysis)
- ***Note, for complex studies it may be useful to attach visit calendars and charts that indicate which interventions will occur for which group at which time

Study Procedures

***Overview*:** Our intervention research study, "Asian Women's Action for Resilience and Empowerment (AWARE): A Stage IA and IB Intervention Development Study, will be comprised on 3 groups of participants:

1) *Asian Women Discussion Group*

In Year 1 (the intervention development phase), we will begin recruiting and screening participants from AWARE. The first 10 women who pass the eligibility screenings and agree to participate the study will be invited to participate as members of the Asian Women Discussion Group, which will serve as a focus group. Although we will administer our preliminary AWARE intervention to the ten selected participants, there is no experimental intervention for the Asian Women Discussion Group. The sole purpose of this focus group is for members to give feedback from the perspective of AWARE intervention participants (as both the Asian Women Discussion Group and the AWARE group must meet the same demographic and clinical criteria). Members in this focus group will be ineligible to participate in the AWARE intervention group (Phase 2 of the study). Members in the Asian Women Discussion Group will attend 10 psychotherapy sessions and an additional discussion meeting afterward, as well as an additional session in September.

2) *AWARE intervention group*

In Year 2 of our study, using Asian Women Discussion Group's feedback and other revisions made during the intervention development phase (in Year 1), we will administer our improved AWARE intervention (Stage IB) to 48 randomly-selected eligible participants. Participants in this group will receive 8 consecutive weekly sessions to receive the manualized intervention. After the last session, participants will be scheduled to return for a 3-month follow-up.

3) *Wait-list (or, delayed treatment) group*

Also in Year 2, the wait-list group will receive the exact same intervention 3 months *after* the start of the AWARE intervention group. The wait-list group will be comprised of 48 randomly-selected eligible participants.

***Detailed Procedure*:**

1. In Year 1, for recruitment of Asian Women Discussion Group participants, we will use first use the database of 720 women who participated in the PI's prior study (AWSHIP).

We will randomly select approximately 100 AWSHIP women (who previously indicated interest in future studies) and ask them to participate in the initial eligibility screening. The function and purpose of Asian Women Discussion Group will be described to each woman by phone, letter, or email.

2. Women from AWSHIP who indicate interest will be invited to call or email the AWARE office or to answer questions on the AWARE website. They will be asked the following 7 initial screening questions and must answer in the affirmative to be eligible for the next recruitment step:
    (1) How or where did you hear about our study? Why did our advertisement grab your attention/our outreach effort interest you?
    (2) What is your sex (should be female only)?
    (3) What is your age as of today (should be between 18 – 35)?
    (4) What racial and ethnic do you identify with (should Chinese, Korean, or Vietnamese)?
    (5) In what country were your mother and father born?
    (6) What languages are you fluent in reading, writing, and speaking?
    (7) Are you currently or have you ever been sexually active?
    (8) Do you currently have a mobile phone (either a regular phone or a smart phone) with a text-messaging plan?

3. Individuals who provide answers that meet the preliminary criteria will receive more detailed information about the study (either by phone or email) within a week.
    a. They will be invited to complete 60-90 minutes of assessments to determine if they meet the clinical criterion (see d) and to ascertain if they meet any of the exclusion criteria (see e).
    b. If they are interested, they will have to come to BUSSW to complete the screening and assessment.
    c. They will sign a consent form to complete the screening and assessment.
    d. In addition to meeting the criteria listed in Step 2, they must also:
        (1) meet the threshold of a traumatic life event, *or*
        (2) have a current diagnosis of PTSD
    e. Women who endorse any of the following items will be ineligible for the study:
        (1) significant current risk of homicidal or suicidal behavior (deliberate self-injury where there is at least some admitted or inferred intention to die)
        (2) presence of schizophrenia, schizoaffective, or organic mental disorders using DSM-IV criteria
        (3) women of mixed race (i.e., do not identify as 100% Chinese, Korean, or Vietnamese or a mixture thereof)

(4) victims who have experienced natural disasters or other non-violent trauma only (i.e., have not been traumatized by physical or sexual violence)
(5) women who are currently victims of severe Intimate Partner Violence (IPV) using The Revised Conflict Tactics Scale (CTS2)

f. They will be paid $20 to complete the screening and assessment.

4. We expect that approximately 90 participants will attend the initial screening, that 33% (n = 30) of those women will meet all inclusion & exclusion criteria on the initial screening, and that 33% (n = 10) of eligible women will agree to be in Asian Women Discussion Group.

   If 10 individuals are not found in the first recruitment effort, secondary recruitment efforts will take place: (1) Community Advisory Board (CAB) members will advertise in their organizations and provide locations for API women to screen for the study. (2) We will use our existing contacts from AWSHIP (20 community organizations and 8 local universities) to explain the purpose of AWARE and ask for their permission to advertise our study through group emails, newsletters, and job advertisements. (3) We will launch AWARE recruitment through the AWARE website (www.bu.edu/aware) and the AWSHIP Facebook and Twitter pages. (4) We will also ask each woman who has agreed to participate in Asian Women Discussion Group to refer a friend. This word-of-mouth strategy was very effective for AWSHIP and successfully contributed to one third of the final sample.

5. Individual participation in Asian Women Discussion includes:
   a. Written consent to participate, including consent for audiotaping of each session
   b. Participation in 90-minute focus group sessions each week (for a total of 10 weeks plus an additional post-intervention discussion meeting and an additional September "check-in" session) with 9 other Asian Women Discussion Group members and a clinician, covering topics including: Safety, Taking Good Care of Yourself, Compassion, Commitment, Creating Meaning, Setting Boundaries in Relationships, Coping with Triggers, Healthy Relationships, Self-Nurturing, and The Life Choices Game.
   c. $20 payment and $4 transportation reimbursement for each focus group session.
   d. Completion of a weekly Adverse Events Log
   e. Receipt of and response to daily, secure mobile text messages (called "AWARE Stories") in between each weekly session to reinforce participation and adherence

f. Provision of feedback and ideas for improving the intervention experience for subsequent participants (via group discussion and written response).

6. In Year 2, we will recommence our recruitment efforts to identify and enroll eligible women into the intervention group and the wait-list group. The interviews during the screening process will be audio-recorded .Women who will be screened in Year 2 go through the same process as women who screened in Year 1 for Asian Women Discussion Group and must meet the same eligibility requirements (see Step 2 and Step 3).

7. Our goal is to screen about 400 women in Year 2. Of this number, we expect about 30% (n=120) to meet all eligibility criteria. We will randomly select 96 eligible women and assign 48 to the AWARE intervention group and 48 to the wait-list group.

8. Individual participation in the AWARE intervention group includes:
    a. Written consent to participate including consent for the audiotaping of each session.
    b. Completion of a baseline assessment prior to the start of the group sessions.
    c. Participation in 105-minute group sessions each week (for a total of 8 weeks) with a small group of other participants and a clinician, covering topics including: Safety, Taking Good Care of Yourself, Compassion, Commitment, Creating Meaning, Setting Boundaries in Relationships, Coping with Triggers, Healthy Relationships, Self-Nurturing, and The Life Choices Game
    d. $26 payment and $4 transportation reimbursement for each weekly group session and $20 payment and $4 transportation reimbursement for each assessment.
    e. Completion of a weekly Adverse Events Log and a weekly questionnaire on the AWARE stories.
    f. Receipt of and response to daily, secure mobile text messages (called "AWARE Stories") in between each weekly session to reinforce participation and adherence
    g. Completion of assessments upon the last intervention session
    h. Completion of outcome assessments in a follow-up visit 3 months after the last intervention session

9. Individual participation in the wait-list group includes:
    a. Written consent to participate including consent for the audiotaping of each session.
    b. Completion of a baseline assessment prior to the start of the group sessions.
    c. Participation in 90-minute group sessions each week (for a total of 8 weeks plus an additional post-intervention meeting) with a small group of other participants and a clinician, covering topics including: Safety, Taking Good Care of Yourself, Compassion, Commitment, Creating Meaning, Setting Boundaries in Relationships,

Coping with Triggers, Healthy Relationships, Self-Nurturing, and The Life Choices Game

d. $26 payment and $4 transportation reimbursement for each focus group session and $20 payment and $4 transportation reimbursement for each assessment.
e. Completion of a weekly Adverse Events Log and a weekly questionnaire on the AWARE stories.
f. Receipt of and response to daily, secure mobile text messages (called "AWARE Stories") in between each weekly session to reinforce participation and adherence.
g. Completion of assessments upon the last intervention session.
h. Completion of outcome assessments in a follow-up visit 3 months after the last intervention session.

F.5. Primary outcomes

Indicate in the box below anticipated primary and secondary outcomes if applicable

Primary outcomes: decrease in HIV risk behaviors, increase in HIV knowledge, increase in self-efficacy in negotiating safer sex

Secondary outcomes: decreased psychiatric symptom severity and decreased substance use

F.6. Surveys, interviews, questionnaires, etc.

You must attach to this application all surveys, interviews, questionnaires, focus group outlines, etc. that will be used in this study. The IRB must review these materials as part of its review. Failure to provide this information could result in a delay in IRB review. If some of the materials are not finalized- submit the DRAFT versions. The final versions will need to be approved by the IRB via an amendment PRIOR to use.

X I have attached all surveys, interviews, questionnaires, data collection forms that will be used in this study

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Section G: Sample Size /Data Analysis

G. 1. Sample Size

Indicate in the box below how many subjects you anticipate will be enrolled in this study (or how many records you will review). If this protocol involves more than one cohort or study phase please specify anticipated sample size for each cohort /study phase. If this study involves multiple experiments you may attach a table summarizing anticipated enrollments by experiment and subject category.

The participants for the intervention program, **A**sian **W**omen's **A**ction for **R**esilience and **E**mpowerment (AWARE) will be comprised of 106 women in total: 10 in the Asian Women Discussion focus group, 48 in the intervention group, and 48 in the wait-list group. The 10 women in Asian Women Discussion Group will participate in the focus group prior to the pilot randomized clinical trial (RCT). We will launch the AWARE campaign to reach out to API women in the greater Boston area and enroll eligible women in our study, using a two-armed randomized design: (1) a group that will receive the 10-session AWARE intervention (n=48) and (2) a wait-list control group who will receive no treatment (n =48). In order to successfully recruit the 96 AWARE participants, we estimate screening 500 women in the community.

G. 2. Sample size justification

Indicate why you chose the sample size proposed. Provide your sample size calculations. If this is a pilot study, this justification does not necessarily require a formal sample size calculation, but should provide a rationale for choosing the sample size proposed (e.g. to estimate a mean to a certain accuracy, to determine if the response rate is above a certain percentage, etc.) **Note: Once the IRB approves a certain study sample size then you may not enroll beyond that sample size without first obtaining approval from the IRB.** **** In determining your sample size be sure to allow for screen failures and study drop-outs in your calculations. Explain how many evaluable subjects you will need to end up with to answer your study question and how many subjects you will need to enroll and consent to achieve this number. The IRB counts study subjects a being enrolled once they have consented.

Our study is a pilot study which does not require a formal sample size calculation.

G. 3. Data Analysis

Provide a description of your plan for data analysis.

- State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance).
- Which is the PRIMARY comparison/analysis?
- How will the analyses proposed relate to the primary purposes of your study?
- If you are doing qualitative research please state how comparisons will be made.

We will use both qualitative data analysis and quantitative analysis in this study. Phase 1 is the development of AWARE protocol stage. Thus, we will use qualitative feedback from Asian Women Discussion Group members in the process of developing the protocol.

Data analysis for Aim 1 (year 1):

Qualitative data analysis: We will analyze Asian Women Discussion Group's qualitative feedback using grounded theory to further enhance the cultural context component of our intervention. We aim to identify the core variable(s) (or basic social processes that Asian Women Discussion Group members express) by employing the constant comparative method, 3 levels of coding, memoing, and theoretical sampling—which are all features of grounded theory. At least 3 research team members will utilize the constant comparative method to analyze Asian Women Discussion Group data in the following three steps:
(1) emerging themes (substantive codes) from transcripts of initial interviews and each focus group and Asian Women Discussion Group member's written feedback will be identified; (2) these themes will then be collapsed into larger groups (categorical codes) based on common content; and (3) these categories will be collapsed again to develop level-three (theoretical) codes. Each member of the analysis team will use memoing (i.e., writing notes that serve to connect and elucidate theories) throughout the processes, while assessing each other's inferences to confirm results. The transcripts will be analyzed using NVivo 9, a qualitative data analysis program. Theoretical sampling (i.e., conducting follow-up interviews) will be utilized to clarify and densify codes as needed. Coding, categorization, and interpretation of the data will be utilized using a template approach that allows for the identification of domains of themes relative to prescribed areas of inquiry. In order to increase reliability of the study, another researcher will review both the core variables and the overall categories. The analysis will enable the research team to better understand Asian Women Discussion Group members' perceptions in the context of the intervention.

Quantitative data for protocol evaluation and participant psychometric monitoring: We will evaluate participants in the Asian Women Discussion Group by comparing the results of pre-intervention and post-intervention psychometric measures. These comparisons will be used to determine if the current protocol is achieving the intervention's goals of providing benefits to participant's mental and behavioral health.

Data Analysis for Aim 2 (year 2):

(1) Feasibility Analysis of group psychotherapy: We conservatively anticipate that 15% of participants will dropout during the 8 week RCT. We also anticipate that another 5% will dropout at the 3-month follow-up evaluation. The first stage of analysis will involve estimating the proportion of women who are eligible and agree to enroll in the study. A 95% confidence interval for the proportion will also be produced. Then, among those who enroll, baseline characteristics will be compared between those randomized to the intervention and those randomized to the wait-list control group to assess balance.

We will estimate the proportion of women who adhere at 8 weeks and 3-month follow-up. Mean proportion of women who attend (at 8 weeks and 3-month follow-up) and 95% confidence intervals will be generated for the total sample and then by groups. We will test the

difference between the participants' adherence rates in the intervention and control group at 8 weeks and 3-month follow-up using a chi-square test. We will then examine bivariate associations between baseline characteristics and attrition (each time point considered separately) using chi-square tests for categorical variables and two sample t tests for continuous variables among all participants. Multivariable associations will be examined using multiple logistic regression models for adherence by group, relating those characteristics that were significant in bivariate analysis to attrition, if sample size permits.

(2) Feasibility Analysis of AWARE Stories (Hypothesis for secure mobile messaging): Higher level of satisfaction and higher utilization of secure text messages are positively associated with group psychotherapy attendance. Ordinal chi-square tests will be used to examine the association between ordinal scale (1-4) of messaging satisfaction and utilization questions and psychotherapy attendance.]

(3) Safety analysis (Hypotheses for safety): For the safety measure, participants will be asked to keep a Weekly Adverse Event Log for measuring safety outcomes (including IPV, suicidal ideation, suicide attempts, and self-mutilation). Our hypotheses are: (A) The AWARE group will have statistically significant lower proportions of suicidal ideation, suicide attempt, and self-mutilation at 8 weeks and 3-month follow-up, compared to baseline. (B) There will be no increased frequency of IPV among the AWARE group between the baseline and post intervention. McNemar's tests will be used to test both (A) and (B). Safety outcomes are measured as developments of adverse event outcomes over the course of the study. These include: (1) suicidal ideation, (2) suicide attempts, (3) self-mutilation, (4) and frequency of IPV. We will estimate the proportion of each adverse event at 95% confidence intervals for participants in the intervention group. We will employ McNemar's tests to compare the proportions of each adverse event in the AWARE group at baseline to the ones in the wait-list group. In addition, mixed effects models for adverse event outcomes will be performed, adjusting for baseline characteristics, such as psychiatric diagnosis severity and substances use, to measure the impact of the baseline characteristics on adverse events and also the pattern of change in adverse events from baseline to the post-intervention follow-up.

Evaluation of Pilot RCT Analysis: We will use an intention-to-treat (ITT) analysis, which indicates all women who are randomized will be included for analysis. To test the success of the randomization, prognostic factors including baseline education, psychiatric diagnosis severity, and substance use will be compared between participants in the intervention group and wait-list group using chi-square tests. Baseline characteristics that show imbalance between groups will be adjusted in multivariate regression models. The efficacy outcome variables will be analyzed as either dichotomized or continuous variables. For PTSD, continuous measures of the CAPS will be assessed. In order to sensitively capture any changes in PTSD scores, continuous measure will be chosen. For HIV outcomes, we will use both dichotomous and continuous variables to measure status and severity of the outcomes at baseline, 8 weeks, and 3-month post-test. Mixed effects models will be used to compare the pattern of change in dichotomous and continuous outcomes over time between groups using normal and logit links, respectively. We will first use an unstructured covariance matrix to

account for correlation between repeated measurements in the same participant and compare it to other covariance structures, using goodness of fit. The most suitable covariance matrix will be chosen for the final model. The same approach will be followed for secondary outcomes. All statistical testing will be performed at the significance level of 0.05 using SAS 9.3.102 Additionally, in order to explore whether compliance affects outcome measures, we will compare the sexual risk behavior, psychiatric severity, and substance use measures between those who drop out versus those who complete the intervention using two-tailed, independent samples t-tests.

Data analysis for Aim 3 (year 2 and 3):

Evaluation of Pilot RCT Analysis: We will use an intention-to-treat (ITT) analysis, which indicates all women who are randomized will be included for analysis. To test the success of the randomization, prognostic factors including baseline education, psychiatric diagnosis severity, and substance use will be compared between participants in the intervention group and wait-list group using chi-square tests. Baseline characteristics that show imbalance between groups will be adjusted in multivariate regression models. The efficacy outcome variables will be analyzed as either dichotomized or continuous variables. For PTSD, continuous measures of the CAPS will be assessed. In order to sensitively capture any changes in PTSD scores, continuous measure will be chosen. For HIV outcomes, we will use both dichotomous and continuous variables to measure status and severity of the outcomes at baseline, 8 weeks, and 3-month post-test. Mixed effects models will be used to compare the pattern of change in dichotomous and continuous outcomes over time between groups using normal and logit links, respectively. We will first use an unstructured covariance matrix to account for correlation between repeated measurements in the same participant and compare it to other covariance structures, using goodness of fit. The most suitable covariance matrix will be chosen for the final model. The same approach will be followed for secondary outcomes. All statistical testing will be performed at the significance level of 0.05 using SAS 9.3.[102] Additionally, in order to explore whether compliance affects outcome measures, we will compare the sexual risk behavior, psychiatric severity, and substance use measures between those who drop out versus those who complete the intervention using two-tailed, independent samples t-tests.

Section H: Potential Risks/ Discomforts

H.1. Description of Risks or Discomforts

In order to approve a study the IRB must be able to determine that "**Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.** In the box below list the possibilities for risk or harm to subjects as a result of participation in the research. Be sure to include physical harms, discomforts, hazards, or inconveniences. Be sure to include the potential for legal or social harms (i.e. loss of confidentiality). **For each harm listed, indicate measures that will be taken to prevent or minimize the effects of all of the potential the hazards, discomforts or risks.**

Potential Risks to Subjects: As potential risks, some participants may be uncomfortable discussing topics pertaining to sexual behaviors and mental health issues. This is especially true for API women, who associate the topic with themes such as stigma and shame. Additionally, Asian Women Discussion Group members may be uncomfortable discussing these topics in a group setting in front of their peers. Given the sensitive nature of the discussion topics, some women may feel traumatized when discussing their experiences. Seeking Safety (the foundation of AWARE) is particularly designed to reduce to feelings of discomfort and shame for women. Instead of highlighting past traumatic experiences, which can be seen as demoralizing for participants, SS focuses instead on potential for the future. Additionally, a licensed therapist will guide and conduct each session with the participants, ensuring that their discomfort is minimized and that the discussions are handled in a sensitive and appropriate manner.

If any woman (including women found ineligible during the initial screening or eligible women during the course of the intervention) reports current severe intimate partner violence (IPV), appropriate referrals additional preventive and clinical services will be provided.

All sessions will be led by a licensed therapist. These sessions will be recorded and safely stored in a password-protected server, and therapists will work closely with and be monitored by the principal investigator. Participants will be asked to read and sign statement of informed consent explaining privacy protections and confidentiality protections. If participants experience discomfort and wish to discontinue the treatment, they will be able to withdraw from the study or refuse to complete a session. Additionally, if participants begin to show symptoms of depression, self-harm, or suicidality, that the therapist leading the group believes warrants treatment they will be withdrawn from the study and referred to a hospital for alternative treatment, which includes treatment at BU Medical Center (BUMC), South Cove Community Health Center, or South Shore Mental Health, the latter two where we have advisors (Mr. Paul Shaw and Dr. Catherine Vuky).

During the course of each SS session, the therapist will take note of each participant to ensure that none exhibit traits of a deteriorating condition. Participants in crisis (e.g. exhibiting symptoms of imminent risk to self or others, psychotic symptoms, safety concerns) will be immediately referred to a hospital to ensure proper treatment and safety. Participants who are not deemed to be in an emergency situation but are showing symptoms of deterioration (as determined by the licensed therapist) will be closely monitored and, if appropriate, considered for referral for alternative treatment. All decisions will be made jointly by the therapist and the principal investigator.

"AWARE Stories" via secure mobile messaging. We aim to enhance the quality of our mental health intervention by supplementing it with a secure messaging application. We will write and use text messages that are closely tied with our weekly session topics to stimulate aspects of psychotherapy outside the weekly group sessions. We will utilize Doc Halo, a secure mobile messaging application, and SMS as message delivery platforms. Participants will be given the

option to either receive the messages through Doc Halo, SMS or both. The overall secure mobile messaging system through DocHalo will consist of 2 components: (1) a text-message delivery/receipt platform; and (2) a research team member who can be reached for any technical problem or general questions related to intervention. No participant information other than their cellphone number will be used in the services of Doc Halo. This information will be strictly confidential and will not be used for any other purposes. This application is HIPAA-compliant and encrypts all messages to ensure security. Participant cellphone numbers will be stored behind a password protected login known only to staff members of the AWARE Study. This system works for smartphones only. Participants without smartphones will be given the option to opt out of receiving the AWARE stories or to receive messages through SMS. Participants will access Doc Halo or their SMS daily to read secure messages from our team. We will send text messages (called ―AWARE Stories) every day at noon, between the weekly group therapy sessions (see diagram below).

We named these messages ―AWARE Stories because we will use actual quotes from API women chronicled in our AWSHIP qualitative data to match the upcoming week‘s core elements. These messages will also include a brief summary of each week‘s content to reinforce the intervention lesson, a brief summary of the upcoming session, and reminders about the weekly group psychotherapy time. We will test whether satisfaction and use of AWARE Stories are correlated with group psychotherapy attendance.

We will emphasize that for this pilot study, the secure messaging feature is not meant to be interactive; rather, it summarizes each session's themes and shares the real-world stories of API women. However, in the event that participants reply to us with strong emotions or comments, we will respond to them in a sensible and appropriate way as soon as we receive text message replies. We have prepared 20 plausible scenarios and responses in the event that participants send us text messages in regard to mental health status, traumatic events, substance use, and suicidality (This plausible scenarios can be found in Human Subjects that was submitted to NIH in the grant application, which are attached in this email).

Withdrawal from AWARE: If a participant wishes to withdraw from the study, alternative treatments and procedures will be suggested. If a participant expresses discomfort at any stage in the study, the therapist will make efforts to make the sensitive topics more comfortable for women to discuss. Additionally, the feedback collected from the end of each Asian Women Discussion Group section as well as individual concerns will be consulted to ensure that therapists are conducting each session in a way that makes participants feel more engaged.

Risks to Confidentiality: All electronic data collected from each session will be coded and stored in a locked file accessible only to research staff to ensure confidentiality. The locked files will be password protected and hosted on a BUSSW server. Names will be removed from data files and will not be published in articles, reports, or publications to ensure privacy of the participants. Research assistants and staff members working on the study will be educated

about the importance of strictly protecting participants' rights to confidentiality. The study site, and the principal investigator, has experience in managing confidential participant information. Procedures similar to those used for the AWSHIP project will be put in place to avoid providing information to other parties.

H.2. Data and Safety Monitoring Plan (DSMP)

For all studies that involve greater than minimal risks you must provide a data and safety monitoring plan. You may provide this in the box below or attach it as a separate document. The DSMP must minimally state

- The anticipated risks and what safety assessments that will be performed to monitor for those risks
- Who specifically will be monitoring the data and the frequency of the monitoring
- A clear description of any safety findings that would occur that would cause the study to be suspended

Please contact the IRB at 617-358-6115 for more information about DSMPs.

Data Safety and Monitoring Plan

Procedures for Monitoring Participant Safety

Safety Precautions. The following procedures will take place in order to ensure data integrity and participant safety during AWARE. The principal investigator will be in charge of overseeing and ensuring the integrity of study data and participant safety.

a) The biggest potential risk to our study participants is safety. In order to ensure safety, all study eligibility criteria screening will first be conducted by trained research assistants. The study eligibility criteria excludes women who have a significant current risk of suicidal/homicidal behavior or a history of schizophrenia-spectrum diagnosis—if a participant begins to demonstrate symptoms of these behaviors/diagnoses, they will be referred to a higher level of treatment or care. Therapists will be tasked to monitor the condition of all participants during each session to ensure that none are at a safety risk.

   Additionally, if an AWARE participant reports severe intimate partner violence (IPV) during the course of the intervention (see item c under "Reporting Adverse Events," below), the therapist will contact the appropriate external referral network to provide for additional needs of the participant. As long as additional supports for the participant are adequately established, she will be able to continue participating in the intervention.

b) Therapists will meet with the PI on a weekly basis to discuss participant conditions and safety issues during both the focus group section as well as the pilot RCT. They will integrate feedback to ensure that participants feel safer and more comfortable. A written report will be produced during each meeting in order to record potential adverse events, safety risks/issues, and participant conditions.

Quantitative data. A comprehensive data management plan will be developed under the guidance of Drs. Hahm and Hien. CASI data will be checked; any discrepancies will be identified and corrected by two research assistants. This plan will ensure high quality data through the use of computerized systems with appropriate data management procedures. To maintain confidentiality of study participants, all data will be made no – just that you will separate identifying information from the data. Furthermore, electronic survey data without identifiers will be stored at two secure locations: the Boston University School of Social Work server and the Boston University School of Public Health Data Coordinating network. Only authorized users who are part of the designated research team will have access to the database. The data will be backed up daily; backup tapes for Boston University are stored in an off-site fireproof safe.

Qualitative data. A comprehensive qualitative data management plan will be also developed by Drs. Hahm and Hien. While qualitative data reports may include segments of individual interviews, any individual identifying information will be deleted. Individual interviews will be transcribed into separate Microsoft (MS) Word documents, each labeled with a unique identifier linking it to the participants' survey data. The rest of the qualitative DSMP will be identical to the quantitative DSMP.

Reporting Adverse Events

This study carries some risk of development of suicidal ideation, suicide attempts, and self-mutilation as adverse events because the women eligible to participate have PTSD or a history of violent trauma. In order to address this risk, we will evaluate potential development of these adverse events at baseline, 8 weeks, and the 3-month follow-up, as well as informally monitoring participant condition on a weekly basis. Participants in the wait-list group will also be assessed for adverse events over the phone at 3 weeks and 6 weeks after the start of treatment for the intervention group. Participants will also be asked to keep a Weekly Adverse Event Log to measure safety outcomes. In addition, since our screening measures may detect suicidal risk and intimate partner violence, we will also provide appropriate care as necessary. We will use the following assessments:

a. Self-mutilation: We will assess self-mutilation using the Columbia-Suicide Severity Rating Scale (C-SSRS). The C-SSRS is a scale administered by a trained individual to assess past suicide attempts and severity of suicidality. Questions address suicidal ideation, intensity of ideation, non-suicidal self-injury, and actual suicide attempts. Questions have either yes/no answers or answer choices scored on a severity of 1-5. The scale exhibits a moderate to high internal consistency, with Cronbach's alpha of 0.7, 0.7, and 0.9, respectively for three existing studies.

b. Suicidality: We will also assess suicidality using the C-SSRS (see item a, above).

c. Intimate Partner Violence (IPV): We will assess IPV using the Revised Conflict Tactics Scale (CTS2). The CTS2 is a self-administered questionnaire which measures the extent of partner conflict and negotiation tactics used. A scale of 0 to 7 to rate 78 relationship behaviors based on frequency. The items belong to the following categories: Negotiation, Psychological Aggression, Physical Assault, Sexual Coercion, and Injury. Cronbach's alpha coefficients range from 0.86- 0.95. Those who meet the criteria severe IPV will be excluded. Women who report 1 or higher (i.e., "My partner

did this to me one or more times") for any items in the "Severe" subscale of the Physical Assault, Sexual Coercion, and Injury scales will be excluded from the study (these items are bolded and highlighted on the CTS2, enclosed). Examples of "severe" items include "My partner slammed me against a wall" and "My partner beat me up." We will provide appropriate referral sources for additional preventive and clinical services for women who meet criteria for severe IPV at any time during the intervention.

If a participant is determined to be at serious risk for suicidal ideation, suicide attempts, self-mutilation, or severe IPV at any assessment point (clinical screening, baseline, 8 weeks, and 3-month follow-up), or through the Adverse Event Log, weekly contact, wait-list group follow-up (at 3 weeks and 6 weeks after randomization), or text messaging, the therapist will call Dr. Hahm immediately by telephone. Dr. Hahm will then call the participant and immediately and assess suicide risk. If risk is determined to be present, the following protocol will be implemented depending on level of risk:

(1) Mild risk (e.g. suicidal ideation present without presence of current plan, low intent, presence of hope, no current means).

a. The participant will be encouraged to call the local Psychiatric Emergency Service (PES).

b. She will also be encouraged to discuss her feelings with family members or close friends.

c. Follow-up contact will be provided by the therapist until risk is determined to be minimal.

(2) Moderate risk (e.g. suicidal ideation present with additional risk factors: moderate intent, low hope, possible plan and/or possible means).

a. The participant will be encouraged to call the local Psychiatric Emergency Service (PES).

b. If the participant refuses to call PES, we will enlist the assistance of a family member, roommate, or close friend to do so.

c. If the participant refuses to enlist family, friends, or a roommate, or if they are not present, she will be encouraged to have the therapist call for her. Should the participant refuse, and if no one is in the home to ensure ongoing safety, the therapist will make the phone call against her will.

d. A plan for removing from the home any means with which to commit suicide, preferably with the assistance of family or trusted other, will be developed.

e. There will be continuous follow-up phone contact (with the therapist or Dr. Hahm) ensuring the participant's safety throughout the day and then on a daily basis until risk is determined to be mild. Phone calls will then occur less frequently until risk is determined to be minimal. The participant will be told at the outset of participation that, if suicide risk is present and they cannot be reached by phone,

the local safety authority or police will be called.

(3) High risk (e.g. suicidal ideation present with several additional risk factors: high intent, no hope, a definite plan, and current means).

a. The participant will be encouraged to call the local emergency room (ER).

b. If the participant refuses to call the local ER, she will be encouraged to allow the PI or therapist to make the ER call. Should the participant refuse, the therapist or PI will make the phone call against her will. They will send an ambulance or unit to the home.

H.3. Study Monitoring

For greater than minimal risk studies NIH and/or the IRB may require data/safety review by a Data and Safety Monitoring Board (DSMB), a Data Monitoring Committee (DMC) or an Independent monitor. *Sometimes the IRB or sponsor will also require that the study be monitored by an "outside" monitoring group. (check all that apply)*

X There are no plans for independent data and safety monitoring. The PI will be responsible for managing unanticipated problems and adverse events and for quality monitoring of the study.

___ This study will have an independent Data and Safety Monitoring Board. Attach the DSMB charter.

___ This study will have an independent Data Monitor. (Provide information about the monitor in the box below.)

___ This study will be monitored by an outside monitoring group/organization.

Data Safety and Monitoring Plan

Procedures for Monitoring Participant Safety

Safety Precautions. The following procedures will take place in order to ensure data integrity and participant safety during AWARE. The principal investigator will be in charge of overseeing and ensuring the integrity of study data and participant safety.

a) The biggest potential risk to our study participants is safety. In order to ensure safety, all study eligibility criteria screening will first be conducted by trained research assistants. The study eligibility criteria excludes women who have a significant current risk of suicidal/homicidal behavior or a history of schizophrenia-spectrum diagnosis—if a participant begins to demonstrate symptoms of these behaviors/diagnoses, they will be referred to a higher level of treatment or care. Therapists will be tasked to monitor the condition of all participants during each session to ensure that none are at a safety risk.

Additionally, if an AWARE participant reports severe intimate partner violence (IPV) during the course of the intervention (see item c under —Reporting Adverse Events,‖ below), the therapist will contact the appropriate external referral network to provide for additional needs

of the participant. As long as additional supports for the participant are adequately established, she will be able to continue participating in the intervention.

b) Therapists will meet with the PI on a weekly basis to discuss participant conditions and safety issues during both the focus group section as well as the pilot RCT. They will integrate feedback to ensure that participants feel safer and more comfortable. A written report will be produced during each meeting in order to record potential adverse events, safety risks/issues, and participant conditions.

Quantitative data. A comprehensive data management plan will be developed under the guidance of Drs. Hahm and Hien. CASI data will be checked; any discrepancies will be identified and corrected by two research assistants. This plan will ensure high quality data through the use of computerized systems with appropriate data management procedures. To maintain confidentiality of study participants, all data will be made anonymous. Furthermore, electronic survey data without identifiers will be stored at two secure locations: the Boston University School of Social Work server and the Boston University School of Public Health Data Coordinating network. Only authorized users will have access to the database. The data will be backed up daily; backup tapes for Boston University are stored in an off-site fireproof safe.

Qualitative data. A comprehensive qualitative data management plan will be also developed by Drs. Hahm and Hien. While qualitative data reports may include segments of individual interviews, any individual identifying information will be eliminated. Individual interviews will be transcribed into separate Microsoft (MS) Word documents, each labeled with a unique identifier linking it to the participants' survey data. The rest of the qualitative DSMP will be identical to the quantitative DSMP.

Reporting Adverse Events

This study carries some risk of development of suicidal ideation, suicide attempts, and self-mutilation as adverse events because the women eligible to participate have PTSD or a history of violent trauma. In order to address this risk, we will evaluate potential development of these adverse events at baseline, 8 weeks, and the 3-month follow-up, as well as informally monitoring participant condition on a weekly basis. Participants in the wait-list group will also be assessed for adverse events over the phone at 3 weeks and 6 weeks after the start of treatment for the intervention group. Participants will also be asked to keep a Weekly Adverse Event Log to measure safety outcomes. In addition, since our screening measures may detect suicidal risk and intimate partner violence, we will also provide appropriate care as necessary.

In the event that an assessment should be conducted remotely, a research assistant will remain on standby throughout the duration of the assessment. Participants will be provided the assistant's contact information and can be reached through this number in the event of an emergency. Upon completion of the survey, the assistant will access the participant's records and determine if any risk factors have been noted. If an adverse event has been detected, the assistant will follow previously established protocol (see details in paragraph that follows). If no risk is determined from the survey, the assistant will contact the participant within 48 hours and conduct a brief follow-up risk assessment over the phone

We will use the following assessments to determine participant risk for harm at any point in the study:

a. Self-mutilation: We will assess self-mutilation using the Columbia-Suicide Severity Rating Scale (C-SSRS). The C-SSRS is a scale administered by a trained individual to assess past suicide attempts and severity of suicidality. Questions address suicidal ideation, intensity of ideation, non-suicidal self-injury, and actual suicide attempts. Questions have either yes/no answers or answer choices scored on a severity of 1-5. The scale exhibits a moderate to high internal consistency, with Cronbach's alpha of 0.7, 0.7, and 0.9, respectively for three existing studies.
b. Suicidality: We will also assess suicidality using the C-SSRS (see item a, above).
c. Intimate Partner Violence (IPV): We will assess IPV using the Revised Conflict Tactics Scale (CTS2). The CTS2 is a self-administered questionnaire which measures the extent of partner conflict and negotiation tactics used. A scale of 0 to 7 to rate 78 relationship behaviors based on frequency. The items belong to the following categories: Negotiation, Psychological Aggression, Physical Assault, Sexual Coercion, and Injury. Cronbach's alpha coefficients range from 0.86- 0.95. Those who meet the criteria severe IPV will be excluded. Women who report 1 or higher (i.e., ―My partner did this to me one or more times‖) for any items in the ―Severe‖ subscale of the Physical Assault, Sexual Coercion, and Injury scales will be excluded from the study (these items are bolded and highlighted on the CTS2, enclosed). Examples of ―severe‖ items include ―My partner slammed me against a wall‖ and ―My partner beat me up.‖ We will provide appropriate referral sources for additional preventive and clinical services for women who meet criteria for severe IPV at any time during the intervention.
If a participant is determined to be at serious risk for suicidal ideation, suicide attempts, self-mutilation, or severe IPV at any assessment point (clinical screening, baseline, 8 weeks, and 3-month follow-up), or through the Adverse Event Log, weekly contact, wait-list group follow-up (at 3 weeks and 6 weeks after randomization), or text messaging, the therapist will call Dr. Hahm immediately by telephone. Dr. Hahm will then call the participant and immediately and assess suicide risk.

If risk is determined to be present, the following protocol will be implemented depending on level of risk:

(1) Mild risk (e.g. suicidal ideation present without presence of current plan, low intent, presence of hope, no current means).
a. The participant will be encouraged to call the local Psychiatric Emergency Service (PES).

b. She will also be encouraged to discuss her feelings with family members or close friends.

c. Follow-up contact will be provided by the therapist until risk is determined to be minimal.

(2) Moderate risk (e.g. suicidal ideation present with additional risk factors: moderate intent, low hope, possible plan and/or possible means).
a. The participant will be encouraged to call the local Psychiatric Emergency Service (PES).

b. If the participant refuses to call PES, we will enlist the assistance of a family member, roommate, or close friend to do so.

c. If the participant refuses to enlist family, friends, or a roommate, or if they are not present, she will be encouraged to have the therapist call for her. Should the participant refuse, and if no one is in the home to ensure ongoing safety, the therapist will make the phone call against her will.

d. A plan for removing from the home any means with which to commit suicide, preferably with the assistance of family or trusted other, will be developed.

e. There will be continuous follow-up phone contact (with the therapist or Dr. Hahm) ensuring the participant's safety throughout the day and then on a daily basis until risk is determined to be mild. Phone calls will then occur less frequently until risk is determined to be minimal. The participant will be told at the outset of participation that, if suicide risk is present and they cannot be reached by phone, the local safety authority or police will be called.

(3) High risk (e.g. suicidal ideation present with several additional risk factors: high intent, no hope, a definite plan, and current means).

a. The participant will be encouraged to call the local emergency room (ER).

b. If the participant refuses to call the local ER, she will be encouraged to allow the PI or therapist to make the ER call. Should the participant refuse, the therapist or PI will make the phone call against her will. They will send an ambulance or unit to the home.

Section I: Benefits

I.1. Direct Benefits to Subjects

Indicate in the box below any potential benefit(s) to be gained by the individual subject as a result of participating in the study. *** *Note: payments to subjects should NOT be included as a benefit. Payment information goes into Section L below.*

Participants in the AWARE program (both the intervention group and the waitlist group) may benefit from the adapted SS intervention for API women. SS has had demonstrated efficacy and effectiveness in reduction of clinical symptoms as well as substance use. Although there are some risks associated with the sensitivity of the topic, which has been discussed in Potential Risks to Subjects, they are outweighed by the potential to reduce HIV-risk behaviors, symptoms of PTSD, suicidality, and depression. Participants will also benefit by learning about healthy behaviors. Along with the intervention, participants will have the opportunity to receive secure mobile text messaging, and also have access to mental health professionals throughout the intervention.

I.2. Indirect Benefits

Describe in the box below the potential benefit(s) to society and scientific/medical knowledge from this project.

If this study is successful, it will potentially have a significant impact on reducing the spread of HIV infection and the incidence of psychiatric symptoms among young API women. The information gained from Asian Women Discussion Group will help inform future treatment of a culturally distinct, hard-to-reach population. This preliminary data will be used to support a subsequent R01 to implement a full-scale clustered randomized control trial to test the efficacy of AWARE for API women through University Health Services Centers throughout the US.

I.3. Risk to benefit ratio.

In order for the IRB to approve the IRB must determine that "**Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).** Discuss how the benefits of this study are reasonable in relation to the risks.

Participants have a high likelihood of benefiting from the adapted SS intervention for API women. SS has had demonstrated efficacy and effectiveness in reduction of clinical symptoms as well as substance use. Although there are some risks associated with the sensitivity of the topic, which has been discussed in "Potential Risks to Subjects", they are outweighed by the potential for dissemination of knowledge between the women participating as well as potential methods for reducing sexual risky behaviors in the future. Benefits will also include collection of methods to reach a hard-to-risk, under-studied population and the development of a treatment that has the potential to reduce HIV-risk behavior and suicidality among API women with PTSD or a history of violent trauma. Along with the intervention, participants will receive secure mobile text messaging.

Section J: Recruitment/ Screening /Consenting subjects

J.1. Describe in detail the planned method for recruiting / contacting potential subjects.

(Be sure to include information about how initial contact will be made with potential subjects and by whom)

A copy of all recruitment materials including advertisements, radio ad scripts, brochures, letters, etc. must be attached to this application. Recruitment materials may not be used without IRB approval.

Primary Sample Recruitment. When we were recruiting for the NIMH-funded K01 study (MH086366-01A1) Asian-American Women's Sexual Health Initiative Project (AWSHIP), we

had asked all women if they were interested in participating in a future study. If so, they checked a box that gave us permission to contact them. Out of 720 total AWSHIP survey participants, approximately 80% (n=565) women indicated interest in future studies. We will contact these AWSHIP participants first to be invited for the screening and assessment of the proposed intervention

Secondary Sample Recruitment.

(1) Three members of the Community Advisory Board will advertise in their organizations and provide specific areas for API women to be screened for the eligibility of our study.

(2) Through AWSHIP, we have established contact with more than 20 community organizations as well as 8 local universities for recruitment in Massachusetts. We will meet key informers and explain the purpose of the AWARE project and ask them for permission to advertise our study through group emails, newsletters, and job advertisements.

(3) We will launch AWARE recruitment through our AWSHIP website (www.bu.edu/awship) and AWSHIP's Facebook and Twitter pages.

(4) We will also ask women who agree to participate in the study to refer a friend who may meet the inclusion criteria. This word of mouth strategy was found to be very effective for AWSHIP, successfully contributing one third of the final sample.

J.2. Screening Procedures ____N/A (study does not include screening)

Indicate in the text box below if any screening procedures will be done to determine subject eligibility. The information in this section should be consistent with Sections F2 and F3 (specifically how will you screen people to determine that they meet the inclusion/exclusion criteria.)

Describe any screening procedures, what data will be collected, what data will be retained, whether subjects will be consented prior to screening, and what will happen to subjects' data if subjects "screen out". If you expect a certain number of subjects to "screen out" be sure to allot for these subjects in Section G2 above. **Attach a copy of all screening forms to this application.**

To assess for demographic eligibility, a seven question pre-screening questionnaire will be administered via phone, e-mail, or in-person. An online questionnaire will be used for pre-screenings via e-mail. Participants may also access the questionnaire directly through a web link from the AWSHIP website.

To assess for clinical eligibility, a 60-90 minute screening assessment will be administered in-person. Consent will be obtained prior to the clinical eligibility screening assessment.

J.3. Consent Procedures

Describe in detail in the box below your plans for obtaining informed consent from subjects. Be sure to include the following information

- Who (specifically) will obtain informed consent (these persons must be listed in Section A as investigators)
- How long will subjects have to consider whether or not they wish to participate in the study
- When and how will consent be obtained (in person, by telephone, by mail, by internet, etc.)

We will advertise for API women to participate in free eligibility screening to be done by answering a brief initial screening for demographic criteria. This will assess potential eligibility and exclusion criteria and determine initial study eligibility. Participants who pass this initial demographic criteria screening will then be invited to the office for the clinical criteria screening. These participants must meet the inclusion and exclusion criteria that are outlined in the "Subject Eligibility Criteria" section (pages 1-3). If eligible, the staff member will invite and answer all questions, and after ensuring that all questions have been answered and that the participant understands the requirements and guidelines for the research study, we will obtain written consent from the participant.

****A copy of all consent forms related to this protocol must be attached to this application. Consent form templates are available at the end of this application. No consent forms may be used until they have been approved and validated with an IRB stamp. Validation includes an approval date and an expiration date.**

J.4. Waiver of Documentation of Informed Consent (Verbal Consent/Assent)

Indicate in the text box below if you are requesting a waiver of documentation of informed consent/assent (also called "verbal assent") for this study. The IRB can only allow a waiver of documentation of consent if the study meets one of the two procedures listed below. In the text box explain how your study meets one of the following two criteria [see 45 CFR 46.117(c)] in the text box below:

(1) That the only record linking the subject to the research would be the consent document and the principal risk of having a signed consent form would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject and the research, and the subject's wishes will govern; or

(2) That 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.

N/A

J.5. Waiver of Informed Consent

In order for the IRB to approve waiver of informed consent the IRB must determine that the following criteria under 45 CFR 46.116 (d) (1-4) are met:

a. the study is not greater than minimal risk;
b. that waiving the requirements for informed consent will not adversely affect the rights and welfare of study subjects;
c. that the research cannot be practicably carried out without the waiver of informed consent or alteration of the consent process,
d. that (if applicable) there would be a plan to disseminate pertinent information to study subjects after the study is completed.

If you are requesting that the IRB approve a Waiver of Consent (you will not obtain informed consent from subjects) indicate this in the text box below. Explain specifically why you will not obtain consent.

N/A

J.6. Assent (from Minors) X N/A (study does not involve subjects who are minors)

Indicate in the text box below if you intend to obtain assent from minor subjects. As a rule the IRB requires

- **verbal assent for minors 7-11 years of age** and
- written assent from minors ages 12-17 (unless verbal consent is approved for the parents/adult subjects (see Section J4 above)

** Be sure to discuss any plans for obtaining consent/assent from pregnant minors.
If you do not plan to obtain assent from subjects who are minors please explain why

N/A

J.7. Consent by substituted judgment

Indicate in the text box below if you intend to obtain consent from a legally authorized representative for cognitively impaired/decisionally impaired subjects. Be sure to include information about how you will ascertain whether or not subjects are capable of consenting themselves and how you will determine who may provide consent for them. ***Note: consent can only be obtained from someone other than the subject with specific IRB approval.**

N/A

Section K- Confidentiality

K.1. Confidentiality of the data

Data is considered identifiable if it

- contains any subject identifiers, OR
- if the data can be linked to subject identifiers via a mastercode OR

- if subjects can be identified via deductive disclosure (combination of the data elements).

In the box below, clearly specify whether any subject data will be recorded in a way that it is identifiable (even temporarily). Specify whether study data will be identified by specific subject identifiers (name, medical record numbers, etc.) or by any study IDs that can be linked to subjects via master-codes. Verify that the study data or combinations of data will not allow subjects to be identified (i.e. initials and birthdates). For data being collected by an online survey service such as PsychSurvey or Survey Monkey, for the study data to be anonymous you must confirm that you will utilize that you will use the anonymity feature provided by these sites from the onset of the study.

(Check all that apply)
___ Study data will all be RECORDED as anonymous (there will be no way to link subjects to their study data even temporarily)

___Study documents such as surveys, data collection forms, interview forms etc. contain identifiers that **will allow subjects to be identified** (including subjects name, social security number, medical record number, etc.) If this is your plan then provide a justification in the text box below.

X All study documents will be identified by a unique study ID. The unique study ID will be linked to the subject identifiers via a mastercode. Access to the mastercode will be limited to a few of the researchers. The key to the mastercode that links study data to identifiers will be stored separately from the study data and protected (locked, separate flash drive, etc.)

___ There is a separate plan for how subjects will be identified in study documents (specify in text box below).

In the text box below explain the details of how study data will be recorded based on the information above.

Every person who completes the screening and assessment interview will be assigned a unique ID. All materials associated with that individual will include the unique ID. Identifying information, including name, age, contact information, will not be included on the screening and assessment forms, or later survey forms. A separate electronic file, accessible to selected research personnel, including the PI, will hold the key that links identifying information to the unique ID. To ensure confidentiality, all data collected from each session will be coded and stored in a locked file accessible only to research staff to ensure confidentiality. The locked files will be password protected and hosted on a BUSSW server. Names will be removed from data files and will not be published in articles, reports, or publications to ensure privacy of the participants. Research assistants and staff members working on the study will be educated about the importance of strictly protecting participants‘ rights to confidentiality. The study site, and the principal investigator, has experience in managing confidential participant

information. Procedures similar to those used for the AWSHIP project will be put in place to avoid providing information to other parties.

K.2. Release of identifiable study data.

Explain who will be PROVIDED identifiable research data (including "coded" data). Be sure to include study staff, study sponsors, students, outside institutions, etc. (Note: in most instances NIH and other study sponsors are not provided identifiable study data but they **have access to study data** on-site for monitoring and auditing purposes. The IRB and the other institutional officials also have access to study data for audit and quality assurance purposes.) Include any release of study data into registries or research databases.

See above instructions.

K.3. Storage and destruction of study data

In the text box below explain

- how and where study data will be stored (hard copies in files, on computers, laptops, flash drives, internet site, secure server, etc).
- Who will be responsible for data storage and protection. What steps will be taken to protect the data. **If this study involves the collection and storage of sensitive information such as HIV status, illegal drug use, what extra protections will be put into place to protect the privacy or anonymity of the subjects.
- Indicate the plans for destruction of study data or identifiers. ****Note: Federal regulations require that study data be maintained by the investigator for a minimum of three years following the COMPLETION of the study. FDA regulations may require that study data be retained for significantly longer.**

We will maintain a strict security system to prevent unauthorized access to the data. All precautions will be taken so that only Dr. Hahm and research personnel will have physical access to the computers where the data will be stored until downloaded to the SSW server. Each computer will be configured with secure BIOS to boot the computer and the access will be controlled by complex passwords associated with authorized users and with no obvious association to the dataset. The data will be stored on the SSW file server with access restricted to Dr. Hahm and her research personnel, using Kerberos passwords, behind the BU campus Firewall.

K.4. Certificate of Confidentiality

Do you plan to obtain a Certificate of Confidentiality (CoC) for this study?
_X_ Yes ___No

Note: If a CoC will be obtained then CoC language is required in the consent form.

K.5. HIPAA / FERPA

Investigators who are part of a "HIPAA covered entity" or "covered component" are subject to the HIPAA regulations if they collect "protected health information". Please go to www.bumc.bu.edu/hipaa for more information about HIPAA covered entities. Click here FERPA for more information about FERPA requirements.

K.5.a. Is the PI part of a HIPAA covered entity/component? ___Yes __X_No

Investigators who obtain protected health information FROM HIPAA covered entity /component must comply with HIPAA regulations.

K.5.b. Does this study involve collection of PHI (protected health information) directly from providers who hold the subjects medical, dental, hospital, insurance or other healthcare records. ___Yes ____No

If the answer to K5a or K5b above is YES then you may be required to include HIPAA authorization language in your consent forms or obtain a HIPAA waiver. Please consult www.bumc.bu.edu/hipaa or the IRB office if you have questions.

K.5.c. Does this study involve collection of information from students school /university records?

____ Yes **X** No

If yes, then federal FERPA rules may apply. Provide information in the text box below regarding the plans to obtain this information in accordance with the regulations.

Section L: Costs/Payments

L.1. Costs

In the text box below explain the costs/potential cost that subjects might/will incur as part of the study. Include costs of travel, parking, medication, equipment, internet service fees, etc. How will the costs of research be covered? Will the subjects have to pay any out of pocket expenses? Will the subject's insurance be billed for any research related activities? If yes, indicate specifically which items the subjects (or subject's insurance) will be responsible for and the cost of each. Be sure to include any co-pays, deductibles, out of pocket expenses, etc.

There will be no costs to participation in any phase of this research.

L.2. Payments

In the text box below, state

- Whether or not subjects will be paid to participate.

- If yes, indicate the form of payment; cash, gift certificates, coupons, etc. Indicate the dollar amount or dollar value amount and the distribution plan (one payment, pro-rated payments, payment upon completion, etc.)
- Describe all reimbursements that will be made to subjects including travel, parking, public transportation, taxi vouchers, babysitting reimbursements, etc.
- Explain specifically how and when these reimbursements will be dispersed. Be sure to include the reimbursement plan for early withdrawals. Note: The IRB recommends that payments be pro-rated and not back end loaded as this may be coercive to subjects and make them feel that they cannot withdraw because they will lose their payment.

Participants will receive honoraria for transportation costs ($4) and $20 for the clinical eligibility screening and assessment after they complete the 7-question eligibility screen. For the Asian Women Discussion Group program, participants will receive transportation costs ($4 per visit to BUSSW) and $20 for each focus group session as well as the September check-in session. For the AWARE program, we will pay participants will receive transportation costs ($4 per visit to BUSSW) $20 for the baseline evaluation, $26 per session during the 8 weeks of the intervention, and $20 for each evaluation (8 weeks, 3- month follow-up). All compensation provided will be given in the form of cash except for assessments that are done online. Online assessments will be compensated using a gift card.

L.3. Course credit for students X N/A

In the text box below indicate

- if student subjects are involved and if students will be given class credit for participation in the study.
- Explain how much class credit will be given, how it will be implemented and how the anonymity /privacy of student subjects will be protected.
- An alternate plan for students who do not wish to participate must be provided that is comparable to participation in the study and does not assert undue influence on students to participate in the research.

Section M: Genetics X N/A

M.1. Description

In the text box below indicate whether this study involves genetic testing (analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes for clinical or research purposes. Such purposes include predicting risk of disease, identifying carriers, and establishing prenatal and clinical diagnosis or prognosis. Prenatal, newborn, and carrier screening, as well as testing in high risk families and tests conducted for somatic mutation or polymorphism and forensic purposes are included. Tests for metabolites are covered only when they are undertaken with

high probability that an excess or deficiency of the metabolite indicates the presence of heritable mutations or polymorphisms in single genes.

M.2. Risk of harm

In the text box below discuss the potential for psychological, social and/or physical harm subsequent to participation in this genetic research (for example potential loss of job or insurability if it were disclosed that subjects have condition XXX.) Be sure to consider the following: risks to privacy, confidentiality insurability, employability, immigration status, paternity status, educational opportunities or social stigma.
Indicate the measures that will be put into place to minimize these risks.

M. 3. Results

In the text box below indicate whether subjects will be provided with genetic results. If so, verify that the tests will be CLIA certified and run in a CLIA certified facility. Provide any information about genetic counseling that will be provided. If there is a possibility that a family's pedigree will be presented or published, describe how the family members' confidentiality will be protected.

Section N: Biological samples X N/A

N. 1. Types of Samples

Indicate any types of samples that will be collected as part of the research (check all that apply) Be sure to include samples that will be obtained for the purpose of drug testing or eligibility screening.

___ Blood by venipuncture
___ Blood from indwelling intravenous lines
___ Spinal fluid (lumbar puncture)
___ Urine samples
___ Secretions (such as tears, saliva, etc.)
___ Stool samples
___ Hair samples
___ Other: specify

N.2. Purpose of the sample collection

In the text box below explain the purpose of the sample collection. Will the samples be put into a repository? Will the samples be stored for future use? Will cell lines be developed from the samples?

N. 3. Obtaining/testing samples

In the text box below explain who will obtain the samples, whether they will be obtained directly from subjects, from pathology department or a lab, the qualifications of the person obtaining the samples(if being obtained directly from subjects), how they will be obtained. Explain whether testing of samples will be done by the researchers or by others such as researchers at another institution or an outside lab.

N.4. Identification of samples

In the text box below indicate how samples will be labeled. Will they be stripped of identifiers? Will they be identified by codes that could facilitate a). re-contacting subjects or b) gaining access to private identifiable information about the subject?

N. 5. Use /release

In the text box below indicate whether the sample will be released to anyone not listed on this protocol as an investigator (for example, to a subject's physician, researchers from another institution or the sponsor). If so will the sample be anonymous or coded or labeled with identifiers? Will samples be sold to any third parties? Will subjects be given results from the testing of samples? ***Note: regulations require that if subjects will be given test results or if results will be put in the medical record to be used for clinical purposes then the tests must be CLIA certified.

N.6. Repository/ future use

In the text box below explain the plan/procedures if samples will be put into a repository or banked for future use. Provide details about the repository including the policies for IRB approval for release of samples, how samples will be stored, identified, destroyed, if subjects will be re-consented for future use, etc.

Section O: Drugs X N/A

In the text box below insert any relevant drug information for this study. Attach the investigator's brochure or package insert with this Application.

Section P: Medical Devices X N/A

In the text box below insert any relevant information about any medical devices being used in this study. Attach the device manual or instructions for use (IFU) to this Application.

Section Q: Consent Forms

The following consent forms have been written and attached to this protocol
X Adult consent
___ Parental consent (for child)
___ Child assent 7-11 year old
___ Child assent 12-17 year old
X Screening consent
___ Other (specify)

Section R: Recruitment materials

The following recruitment materials have been attached to this application for review (check all that apply)
___ Brochure
X Flyers/ handouts
___ Radio ads
___ Internet posting
X Email text
___ Recruitment letters
___ Other (specify) _____

Section S: Other attachments

Be sure to attach to this application all of the following **that apply to your study**. Failure to provide all documents can result in a delay in processing your application:

- Grant (federally funded)
- Sponsor's protocol (industry/foundation)
- Detailed protocol (unfunded)
- Human subjects training certificates for all investigators listed in Section A

- All surveys, questionnaires, data collection forms and other instruments that will be used in the study.
- All consent and assent forms
- Recruitment materials
- HIPAA forms
- Letters of permission – If the study is being conducted at a site that is not part of the PI's department it may be necessary to provide the IRB will a letter of permission from the person in charge of the site indicating that it is permissible to conduct research at that site. If the study is going to take place at an external site (i.e. school system, church, clinic, etc. proof of permission to conduct research at that site will be required).

Certification / Signatures

- By submitting this protocol I attest to the fact that all research activities to be implemented related to human subjects have been completely and accurately described herein.

- I agree to conduct the describe research in an ethical manner.

- I agree to comply with all institutional policies and procedures related to human subjects research and will not begin any human subjects research activities until I have obtained full approval from the IRB.

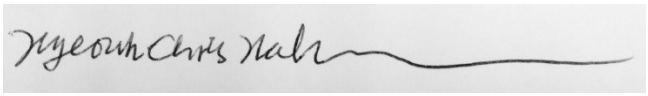
- I agree to conduct the research as described in this protocol and not to make any changes (except to eliminate immediate harm to subjects) without first obtaining approval for the changes from the IRB.

- I agree to immediately report any unanticipated problems involving risks to subjects or others, any subject complaints, and any incidents of non-compliance with the requirements of this protocol as soon as I become aware of them.

- I agree to comply with any relevant HIPAA and FERPA regulations if applicable..

- I verify that all those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial interest disclosure forms and training as dictated at http://www.bu.edu/orc/coi/forms/, and returned the forms to the Office for Research Compliance COI Unit. **NOTE: If anyone checked "yes" to any of the questions on either the FIND1 or NONFIND1 form, the IRB Director will contact the COI office to obtain the disclosure information.**

PI printed name: Hyeouk Chris Hahm

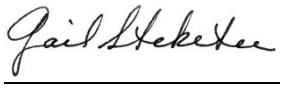
PI: Signature:  *Date: 3/29/13*

FACULTY Research:

The Department Chair signature is required: *This application must be signed by the Department Chair for all faculty researchers. If the PI is the Department Chair then signature by the appropriate Dean is required. Department Chair signature is not required for student research.*

By signing this form you are indicating that you have reviewed the application, the faculty/staff person listed as PI on this protocol is a member of your department, and that he/she is qualified to serve as the PI for this study.

Department Chair (print name) Gail Steketee *Department/School School of Social Work*

Signature:  *Date3/29/13*

STUDENT Research

Student research: Student research must be signed by the faculty advisor AND the designated School IRB pre-reviewer PRIOR TO submission to the IRB. For more information consult "Guidance for Students Conducting Research" at www.bu.edu/irb.

By signing this form you are indicating that you have reviewed the application, that you agree to serve as the Co-PI for this study with the student and that you will be responsible for the ethical conduct of this student's human subjects research. .

Printed name of faculty advisor_____

Signature_____ Date_____

Printed name of the Designated School IRB pre-reviewer. _____

Signature_____ Date_____