

Supplementary Online Content

Rhodes KV, Rodgers M, Sommers M, et al. Brief motivational intervention for intimate partner violence and heavy drinking in the emergency department: a randomized clinical trial. *JAMA*. doi:10.1001/jama.2015.8369

Trial protocol

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

Summarized NIAAA SHIP Study Procedural Guidelines

SECTION 1 INTRODUCTION.....	3
SECTION 2 STUDY DESIGN	3
SETTING.....	3
SPECIFIC AIMS.....	3
EXPLORATORY AIMS	4
IDENTIFYING SUBJECTS.....	6
TREATMENT GROUPS.....	8
SECTION 3 RESEARCH STAFF: RESPONSIBILITIES, TRAINING AND SUPERVISION.....	12
RESEARCH ASSISTANTS.....	12
MOTIVATIONAL ENHANCEMENT THERAPY (MET) THERAPISTS.....	13
SECTION 4 STUDY PROCEDURES.....	14
APPROACH & SCREEN.....	14
ASSESS.....	16
CONSENT, RANDOMIZE & ENROLL	16
TREATMENT PROCEDURES.....	16
SECTION 5 DATA COLLECTION TOOLS & METHODS.....	18
ENGAGEMENT AND STUDY COMPLETION (CODING FOR CONSORT)	18
TABLE OF MEASURES (ASSESSMENT BATTERY).....	24
SECTION 6 PLANNED STATISTICAL ANALYSES.....	27
PRIMARY ANALYSIS: HEAVY DRINKING OUTCOMES.....	27
PRIMARY ANALYSIS: INCIDENCE OF INTIMATE PARTNER VIOLENCE (IPV)	28
SECONDARY ANALYSES OF OUTCOMES.....	29
NO CONTACT CONTROL GROUP	29
PREDICTOR ANALYSES	29
MODERATION ANALYSES.....	29
MEDIATOR ANALYSES.....	30
SECTION 7 PROTECTION OF HUMAN SUBJECTS.....	30
RISK TO PARTICIPANTS	30
ADEQUACY OF PROTECTION FROM RISKS.....	30
RISKS/BENEFITS ASSESSMENT	33
INDIVIDUALIZED SAFE CONTACT.....	33
DATA SAFETY MONITORING BOARD	33
ADVERSE EVENTS AND PROTOCOL VIOLATIONS.....	34
SPECIFIC SUICIDALITY PROCEDURES	34
SECTION 8 SUMMARY OF MODIFICATIONS TO STUDY PROTOCOL.....	36
APPENDICES INDEX	43
SOCIAL HEALTH SURVEY & RESOURCES.....	43
SCREENER'S TRACKING FORM.....	43
ELIGIBILITY ASSESSMENT FORM – CTS2S & AUDIT	43
SAFE CONTACT PLAN.....	43
PARTICIPANT DEMOGRAPHICS SHEET	43
BASELINE WOMEN'S HEALTH INTERVIEW.....	43
FOLLOW-UP WOMEN'S HEALTH INTERVIEW (ACG & BIG)	43
NCCG FOLLOW-UP WOMEN'S HEALTH INTERVIEW	43
TIMELINE FOLLOW BACK CALENDAR FORM.....	43

SCRIPT FOR INTERACTIVE VOICE RESPONSE (IVRS) 43
MET BOOSTER FORM 43

Section 1 Introduction

This is a randomized controlled trial (RCT) of a brief intervention for intimate partner violence (IPV)-involved women patients with problem drinking (defined as the full spectrum of hazardous, harmful, or dependent drinking). Upon completion of the proposed study, we will have high-quality evidence regarding the effectiveness of a low-intensity, gender-sensitive brief motivational intervention, delivered by Motivational Enhancement Therapy (MET) Therapists in the emergency department (ED) setting, for decreasing IPV and episodes of heavy drinking and increasing rates of follow up with resources for IPV-involved women.

There is a strong and reciprocal association between two prevalent public health problems: IPV and problem drinking. Brief interventions in the ED setting have been found to be effective in reducing alcohol consumption to safe levels in hazardous drinkers and in encouraging follow up with resources, but there are no studies evaluating the long-term impact of IPV interventions in health care settings. A concern has been raised that brief motivational alcohol interventions are less effective in women; these mixed results may or may not be due to unmeasured IPV among women drinkers. This question is unanswered as neither IPV nor substance abuse interventions have adequately integrated assessment and treatment for these co-occurring conditions. Based on the available research, we conclude that the proposed study will fill an important gap in the literature by assessing whether a brief motivational intervention in an acute care setting that targets both risks has the potential to reduce heavy drinking and IPV in women.

Section 2 Study Design

Setting

The Hospital of the University of Pennsylvania Emergency Department

The emergency department at the Hospital of the University of Pennsylvania (HUP ED) provides a full range of critical care, medical, surgical and trauma evaluation for the patients requiring emergency care. It is the sole ED and Level 1 trauma center serving West Philadelphia, a 14-square mile urban area with lower socioeconomic status and a population of 204,000. Contiguous to the Penn campus, HUP ED has both acute rooms for evaluation and treatment; an ED fast-track (i.e., non-critical) assessment and a psychiatric emergency evaluation center. It is staffed at all times with multiple fulltime Emergency Medicine physicians, trauma surgeons, nurse practitioners, nurses, and resident physicians. Exam rooms allow privacy during the enrollment, consent, baseline data collection, and brief intervention. When busy, exam areas overflow to use hallway beds but patients can be moved to an adjacent observation area with private rooms for purposes of our MET.

The ED census during the past four years has averaged 55,578 patient visits (minimum [2004] = 52,596; maximum [2007] = 58,152). Approximately 93% of the 33,000 annual ED visits by women are by female patients aged 18 to 65, the population targeted in the proposed study. We believe that given the demographics of the ED population, and using a conservative prevalence range of 5-10% for risk of BOTH IPV and problem drinking, we will have an adequate sample for the study.

Presbyterian Medical Center (PMC) Emergency Department (ED)

The Presbyterian ED, a Level II Trauma center is staffed by University of Pennsylvania faculty and residents. Located approximately 8 blocks away from the HUP ED, Presbyterian ED has similar facilities, private rooms and private spaces for interviewing patients who are discharged.

In CY 2010, there were 38,039 patient visits the Emergency Department at Presbyterian Medical Center. Approximately 77% of the 21,956 annual ED visits by women are by female patients aged 18 to 64, the population targeted in the proposed study. The addition of this site for data collection and recruitment should increase the number of eligible patients we encounter and thus, expedite our study recruitment over the next 2 years.

Specific Aims

Specific Aim #1 Conduct a randomized control trial (RCT) with 600 Emergency Department (ED) patients to assess the effectiveness of a brief motivational intervention (BMI) for decreasing problem drinking and intimate partner violence (IPV)

Conduct a randomized controlled trial with 600 women ED patients to assess the effectiveness of a brief intervention for decreasing problem drinking and IPV (both victimization and perpetration). We hypothesize that at-risk women who receive a brief motivational intervention will have a reduction in primary outcomes of days of heavy drinking (4 or more drinks/day) and incidents of IPV-assessed weekly by an Interactive Voice Response System for 3 months and by follow-up interview at 3, 6, and 12 months – compared to an identically-assessed care group. To identify the impact of assessment alone on these primary outcomes, we will include a no-contact control group that is assessed only at 3 months. All patients will receive standard written referrals.

Construct	Measure	Measure Ref.	# items	Sample Item	Response Type
IPV Frequency	CTS2S	Straus & Douglas (2004)	16	# times partner hit, punched, or beat up.	# incidents
Heavy Episodic Drinking	AUDIT/AUDIT-C	Reinert (2002) Bush (1998)	3	How often do you have 4+ drinks on one occasion?	# heavy drinking days

Specific Aim #2: Assess the impact of the intervention on secondary outcomes

Construct	Measure	Measure Ref.	# items	Sample Item	Response Type
IPV Severity (past wk.) ·Victim ·Perpetrator	CTS2S	Straus & Douglas, 2004	6	#times partner used force to have sex.	#categorized as "severe"
Alcohol quantity/frequency (past wk.)	AUDIT-C	Bush, 1998	3	In the past week, how many days have you had a drink containing alcohol?	#days/week X #drinks/day
Self-Rated Health		Andresen et al. (2003)	1	How would you say your health has been?	Likert (1-5)
Health Behaviors ·Smoking ·Exercise			2	How many days/week do you engage in vigorous physical exercise?	#cigarettes #days exercise
Quality of Life	WHOQOL Qs 1, 5, 8	WHO (2004)	3	How much do you enjoy life?	Likert (1-5)
Relationship Satisfaction	Dyadic Adjust. Scale	Hunsley et al. (1995)	1	Which response best describes the happiness in your relationship?	Likert (0-6)

Exploratory Aims

Exploratory Aim #1: Assess potential mediators of the effectiveness of a brief motivational intervention (BMI) on intimate partner violence (IPV) and drinking outcomes.

Assess potential mediators of the effectiveness of a brief motivational intervention on IPV and drinking outcomes. We hypothesize that important mediators of the effect of the intervention on our primary outcomes will be an increase in women's self-efficacy and rates of engagement with informal and formal social support systems. Engagement with support services will be measured by a woman's report of any in-person contact with a community-based support group, criminal or civil court or treatment program for IPV or substance abuse.

Mediators	Construct	Measure	Measure Ref.	# items	Sample Item	Response Type
Personal Changes	Self-Efficacy	Generalized Self Efficacy Scale	Schwarzer & Jerusalem (1993)	10	I can always manage to solve difficult problems if I try hard enough.	Likert (1-4)
	Motivation to Change importance/ confidence for alcohol/IPV			4	On a scale of 1-10, how important is it to you to take steps to change the conflict in your relationship?	Likert (1-10)
	Steps to Safety	Checklist		12+	In the past 3 months, have you: <input type="checkbox"/> Changed/added locks	# "yes" responses
Social/ Community	Social Support	Social Support Network Scale	Block (2000) Chicago. Women's Health Risk Study	3	Do you have someone you could stay with if needed?	Yes/No Score 0-3
	Engagement with: ·Criminal/Civil Court ·IPV agencies ·Alcohol peer support			2	Have you used any police or court services because of family violence?	Yes/No #instances
Engagement in Treatment (outpatient/ inpatient)	·Alcohol ·Drug ·Mental Health ·Healthcare			4	How many times have you seen a health professional on an outpatient basis for problems with alcohol?	# treatment visits

Exploratory Aim #2: Assess the role of potential predictors/moderators of a brief motivational intervention (BMI)'s effect on primary and secondary outcomes.

Moderators	Measure	Measure Ref.	# items	Sample Item	Response Type
IPV Severity at Baseline (low/high)	Women's Experience with Battering Scale	Smith et al. (2002)	10	I feel like he keeps me prisoner.	Likert (1-6) Score 10-60
	Danger Assessment	Campbell (1986)	20	Does he own a gun?	Yes/No Weighted score
Likely Alcohol Dependence	AUDIT Qs 4,5, 6	Reinert (2002)	3	How often have you needed a first drink in the morning to get going?	Likert (0-4) + or - for dependence
Illicit Drug Use	DAST-10	French et al. (2001)	10	Are you always able to stop using drugs when you want to?	Yes/No use Score 0-10
Depression	CES-D	Radloff (1977)	20	How often have you felt hopeful about the future?	Likert (0-3) Score 0-60 (16+ = depression)

PTSD	Primary Care PTSD Screen	Prins et al. (2003)	4	Have you had an experience that was so upsetting that you have had nightmares about it?	Yes/No Score 1-4 (Score 3+=PTSD)
Sexual Abuse History	GENACIS	Wilsnack & Wilsnack (2002)	2	Before you were 16 years old did someone try to make you do/watch sexual things?	Likert (1-5) (Never/Any)
Partner Drinking	GENACIS	Wilsnack & Wilsnack (2002)	6	When you and your partner quarrel, how often has your partner been drinking?	Likert (1-5) All the time/Most times...

Identifying Subjects

Inclusion Criteria / Justifications

The following are inclusion criteria:

Inclusion Criteria	Measure	Indicator
Female	EMTRAC Medical Record	Gender classification in Social Health Bin; Based on Self-Identification*.
Age 18 years to 64 years	EMTRAC Medical Record	Age / Date of Birth in Social Health Bin
Language	Informal assessment from staff interaction with patient	Ability to discuss Social Health Survey in English with staff.
Cognitive ability	Informal assessment from staff interaction with patient	Patient appears to be oriented to time, place, and person with good recall of recent and remote events. <i>Patient understands consent form content.</i>
Heavy drinking in past 3 months (4 or more drinks on at least one day)	AUDIT/AUDIT-C (Specifically Questions 1, 2 &3)	AUDIT Score \geq 4
Positive screen for IPV by a current or former partner in past 3 months	CTS2S	CTS2S Score \geq 1

*If patient is classified as Female in the Social Health Bin, but identifies as Male upon approach, patient is not eligible to participant. All patients that self-identified patients are eligible to participate, but only patients in the Social Health Bin classified as gender will be engaged.

Exclusion Criteria / Justifications

The following are inclusion criteria:

Exclusion Criteria	Measure	Indicator
Intoxication at time of screening* <i>Subjects need to be sober to participate in the interview.</i>	EMTRAC Medical Record; Physical Examination by Doctor; Staff interaction with patient	Changes in behavior (loud, bad tempered, physically violent); Lack of judgment; Lack of coordination (staggering, fumbling); Decreased alertness (incoherent or slurring); Physical signs (glassy eyes, vomiting); Indicated on EMTRAC that "patient is intoxicated and aggressive with staff."

Exclusion Criteria	Measure	Indicator
Cognitive impairment or psychosis	<u>EMTRAC Medical Record</u> ; Physical Examination by Doctor (clinical assessment); Staff interaction with patient	Patient does not appear to be oriented to time, place, and person with good recall of recent and remote events. May include stroke patients or patients with amnesia/severe memory loss. <u>Unsure that patient understands consent form.</u>
<u>Medically unable due to serious current medical illness or injury*</u> <i>Critically ill or injured will likely be admitted to the hospital**</i>	<u>EMTRAC Medical Record</u> ; Physical Examination by Doctor; Staff determination Patient determination	Triage Class in EMTRAC (Class 1 or 2 are usually too sick); receiving medical care for breathing problems, bleeding, severe infection, severe pain, etc.; too sick or upset to be approached (e.g. moaning, screaming, in pain, sobbing, etc.)
Suicidal or homicidal ideation	<u>EMTRAC Medical Record</u> ; Doctor Determination.	Either noted in EMTRAC or gathered during interaction with patient (ideation must be present or within the last two weeks).
No identifiable residence or contact phone number	<u>EMTRAC Medical Record</u> ; Patient indication	Homeless, no contact numbers
<u>Criminal Justice Involvement/Under arrest at the time of ED visit</u> <i>Likely to be unavailable for follow-up due to incarceration</i>	<u>EMTRAC Medical Record</u> ; Staff interaction with patient	Police guard, handcuffs, Attending notification.
Non-English speaking	Staff interaction with patient.	Able to verbally communicate about Social Health Survey and/or understand consent (includes presence of translator, deaf/mute)
Previously enrolled in the study.	N/A	Staff recognition; Questioning patient regarding previous involvement.
*This status can change over the course of the ED visit; Re-evaluate patients throughout visit if they are initially ineligible.		
**If patient was medically stable enough to enroll in the study, but is then admitted to the hospital, they can remain a study subject if they are discharged from the hospital within 5 days. However, if a patient is discharged to an inpatient mental health or substance abuse treatment facility, they will be excluded from the study, as any long-term results will not be able to be attributed to our brief intervention.		

Please note that if exclusion criteria, such as suicidality or psychosis, are identified AFTER a patient is already enrolled in the study, this person will continue to be enrolled in the study and contacted to participant in follow-up activities. The Only exception to this is when the patient withdraws consent to participant. Our Women's Health Interview documents the treatments and services they use outside of the study protocol.

Targeted Drinking Severity

For purposes of the study, we want a baseline level of at least one incident of heavy drinking >4 drinks/day in the last 3 months, since our primary outcomes are assessed at 3 months. However, it is important to note that EDs see the full range of alcohol abuse severity from hazardous drinking that exceeds recommended safe gender-specific quantity and frequency levels to dependent drinking marked by physiological symptoms of withdrawal. Indeed, an accurate clinical assessment of the extent of alcohol abuse is not always practical in the ED setting. Therefore, to maximize the generalizability of this intervention in the IPV-involved population of female drinkers, beyond our baseline level, we have chosen to include the full range of alcohol abuse severity and to focus on the outcome goal of decreasing episodes of heavy drinking in the previous month that is known to be associated with IPV. For likely dependent drinkers the goals of MET will include abstinence and engagement in treatment and formal social support.

Targeted intimate partner violence (IPV)-involvement (victimization and/or perpetration) in women

For purposes of following 3 month outcomes, we have selected a baseline level of at least one incident of IPV assessed by the CTS2S in the past 3 months. EDs see a wide range of IPV severity from situational couple violence to intimate terrorism; and both men and women can be victims as well as perpetrators of a wide range of abusive relationship behaviors, from emotional abuse to severe physical and sexual violence. While we believe that our MET intervention would likely be equally effective with men, measures for battering (WEB: Smith, 2002) and assessing danger (DA: Campbell, 1986) have been validated only in women and it is well established that a woman's own use of violence puts her at increased risk of victimization (Stith, 2004), so any intervention that decreases a woman's aggression towards her partner will likely prevent future IPV victimization, given that women are more likely to be injured in bi-directional violence (Cascardi, 1992). We have chosen to focus on IPV-involvement, defined as past 3 month victimization and/or perpetration of both emotional and physical abuse in women identified on routine social health screening in the ED. We will use the revised Short Conflict Tactics Scales (CTS2S: Straus & Douglas, 2004) at baseline and as our outcome measure for the frequency, direction, mutuality and severity of abusive behaviors. We hypothesize that a reduction in a women's frequency of heavy drinking will be likely to increase her safety and decrease future incidents of both IPV victimization and perpetration.

Treatment Groups

Brief Intervention Group (BIG): Two hundred forty (n=240) study participants will be randomized into the brief intervention group (BIG). This group will complete the Women's Health Interview and then meet with the MET therapist for a 20 minute, audiotaped intervention. These women will receive a 15 minute phone booster 7-10 days following the ED visit. This group will complete the IVR survey once a week for 12 weeks and follow-up interviews at 3, 6, and 12 months.

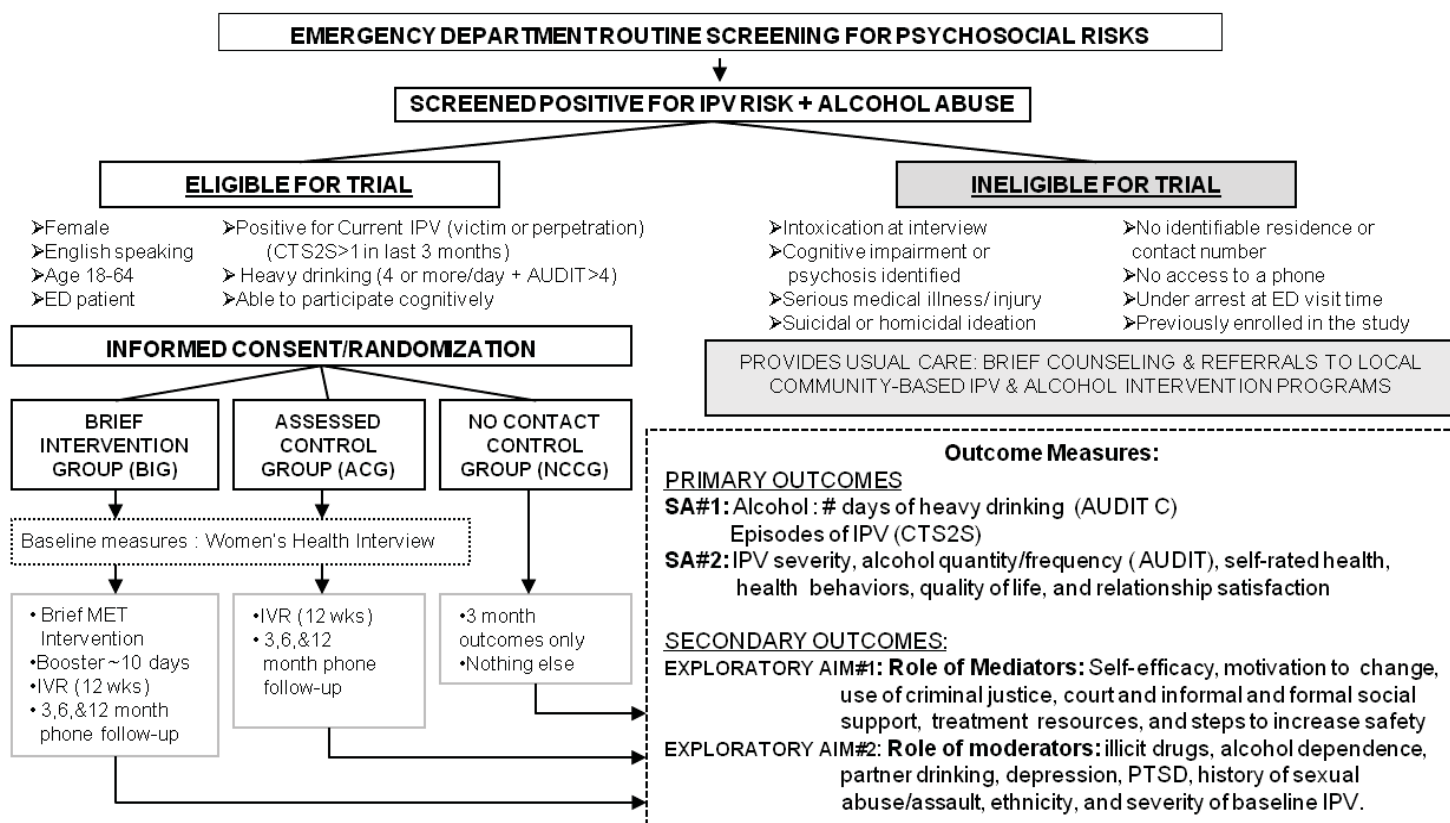
Assessed Control Group (ACG): Two hundred forty (n=240) participants will be randomized into the assessed control group. This group will complete the Women's Health Interview. They will then complete the IVR survey once a week for 12 weeks and follow-up interviews at 3, 6, and 12 months. This group will be offered the MET intervention at the conclusion of their participation.

No Contact Control Group (NCCG): One hundred twenty (n=120) participants will be enrolled into the no contact control group. This group will not be assessed at baseline, beyond the AUDIT and CTS2S to determine eligibility, and will only be assessed for outcomes at 3 months. Their study participation ends after this interview and they will be offered the MET intervention.

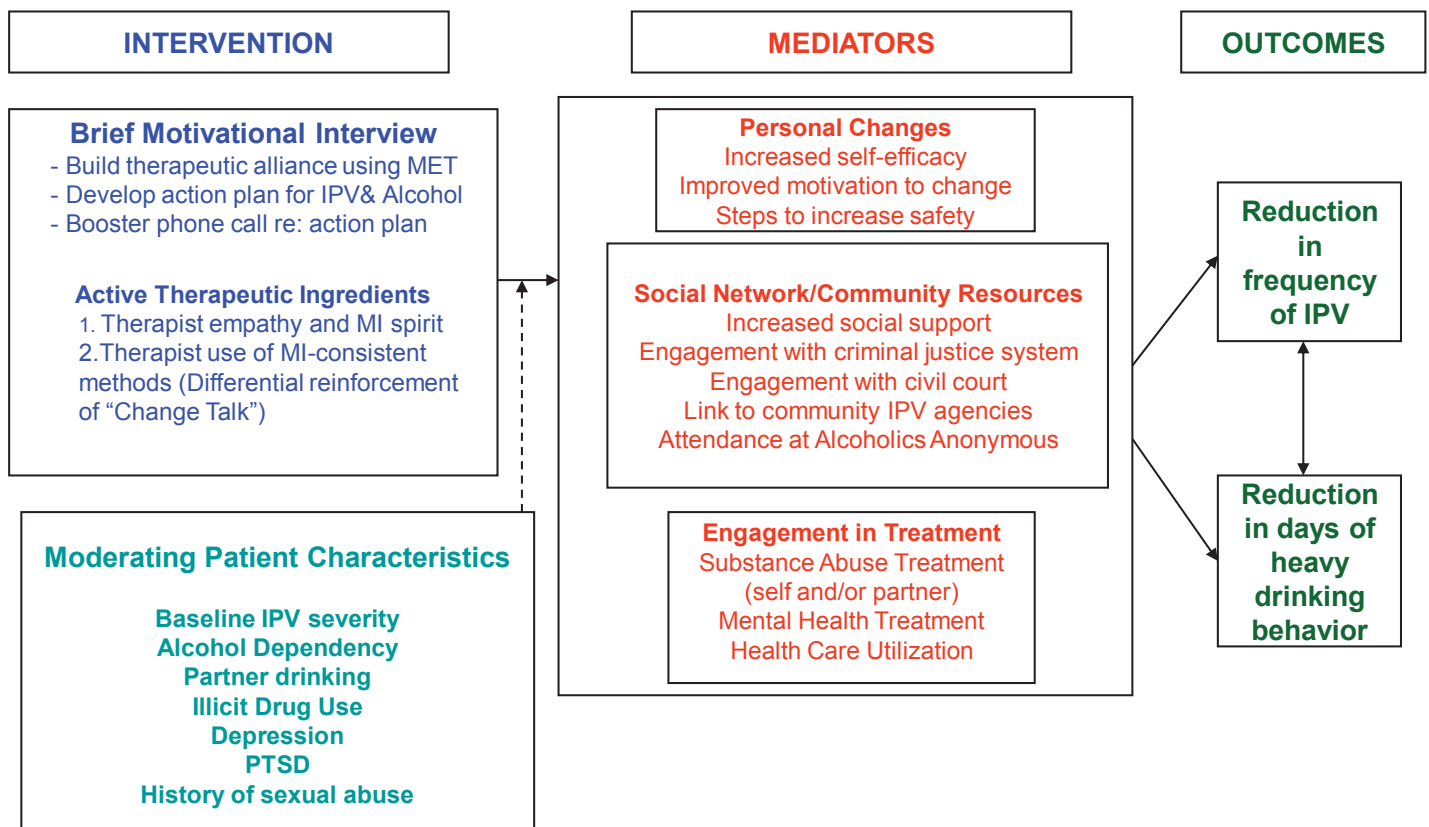
Justification for a No Contact Control Group (NCCG): This control group only has eligibility confirmed at baseline and outcome assessment at 3 months. In previous research, assessed control groups show considerable improvement over time (Monti, 1999; Longabaugh, 2001), leading many alcohol researchers to conclude multiple assessments that include questions about the negative effects of alcohol may in themselves constitute an intervention leading to spontaneous motivations to change self-reported drinking patterns (e.g., assessment reactivity, Mundt, 1995). The no contact control group allows us to separate out the extent to which improvements over time in the intervention and assessed control groups may have been due to repeated assessments and personal contact with assessors.

Flow Diagram of Study

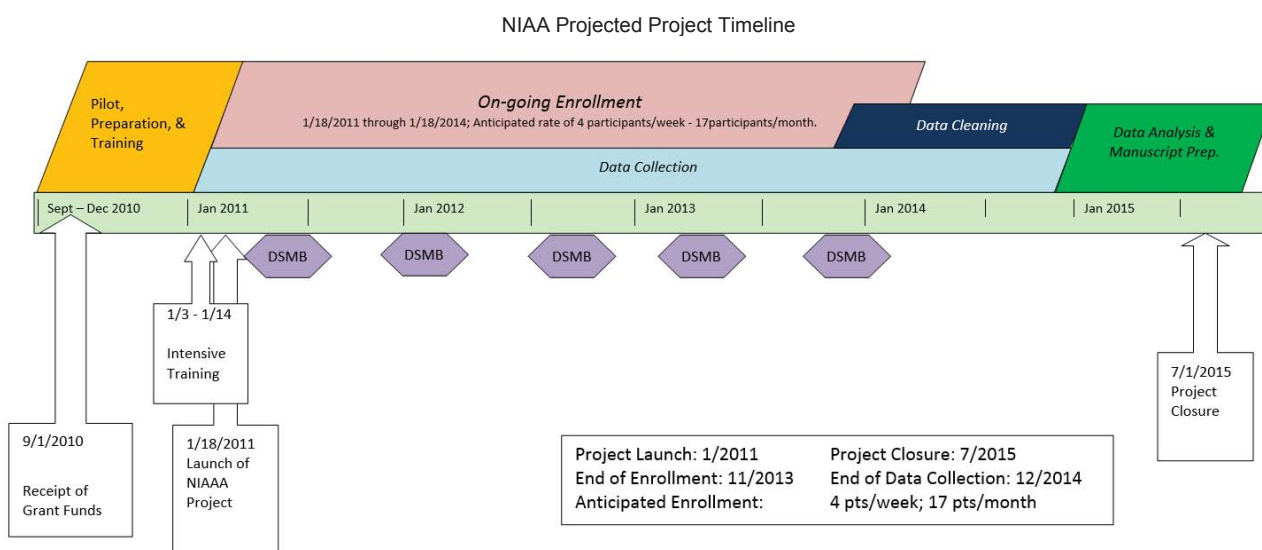
Study Flow Chart



Conceptual Model for Intervention for IPV + Heavy Drinking



Project Timeline



Section 3 Research Staff: Responsibilities, Training and Supervision

This section of the manual describes the two primary research staff involved in the essential administration of study design: Research Assistants and Motivational Enhancement Therapists. All day to day procedural aspects of the study are overseen by a Project Manager who works directly under the Principal Investigator

Research Assistants

Overview

Research Assistants are responsible for screening in the ED as well as other tasks. Research Assistants formally determine eligibility, consent and enroll patients, randomize subjects, and administer the Women's Health Interview. Previous experience with vulnerable populations, with research methods and in clinical settings is desired but not required for prospective temporary, part-time Research Assistants.

Targeted Trainings

Intimate Partner Violence: Research Assistants receive a brief (approximately 1 hour) overview of intimate partner violence. Topics include a discussion on the various types of abuse and necessary precautions in working with this sample.

Institutional Review Board: All Research Assistants complete the Human Subjects Training given by the Institutional Review Board (IRB). This training is provided through the CITI (Collaborative Institutional Training Initiative).

Tasks/ Job Responsibilities

1. Distribution of SHS: *Distribution of Social Health Survey: At HUP, the Social Health Survey (SHS) should be given out by hospital clerks during registration, as part of routine care. At the start of a Research Assistant's shift, he/she should check with the "greeter" in the ED registration area to make sure they are handing out the Social Health Survey and that they have enough surveys on hand. At PMC, research assistants are responsible for the distribution of the SHS.*
2. Review of SHS: Screeners read through the survey and check to see if the patient screens positive for either IPV or Alcohol. Completed SHSs should be reviewed quietly and discreetly. It is encouraged that screeners step out of the room to thoroughly review for and note the following:

Risky Drinking Behavior identified by:

- a. Question 7 – Response greater than or equal to '1'
- b. Question 8 & 9 – Multiplied Responses (drinking days X typical number of drinks) is greater than or equal to '7'.

Potential IPV identified by:

- a. Question 22 through 27 – Response of 'Yes' to any one of these questions
- b. Question 30 – Response of 'Yes'

NOTE: IF patient indicates 'Not Sure' for any of the IPV questions, further probing may be warranted to determine if positive for IPV Risk.

If the patient does not screen positive on the IPV or Alcohol questions, they are not eligible to participate in the study and the Social Health Survey is left in the room for the patient's doctor to use as a part of usual care in the Emergency Department. The patient's involvement in the study ends at that point.

3. Administer Eligibility Assessment: If the patient screens positive for IPV or alcohol (as determined by the Social Health Survey), the Research Assistant administers the CTS2S and the AUDIT to determine eligibility. In the event that anyone is present in the room, the Research Assistant should ask them to leave the room prior to discussing the survey with the patient.

If Research Assistant believes there is any chance that patient will need to leave the ED in the near future (e.g. they will be discharged, they will be admitted to the hospital), provide a brief overview of the study and ask patient for their Safe Contact information *immediately*. Then move into consent process.

4. Consent Eligible and Willing Patients: If the patient meets the eligibility criteria (as determined by the CTS2S and the AUDIT), then the Research Assistant should verify that the patient was not previously enrolled in the study. Immediately after an individual consents to participate in the project, Research Assistants should complete her Safe Contact Form.
5. Randomization: After the participant consents to participate in the research study, the Research Assistant randomizes the participant to one of three possible groups. If the participant is randomized to either the Brief Intervention Group (BIG) or the Assessed Control Group (ACG), the Research Assistant enrolls the participant into the IVRS system and conducts the first phone call with the patient, then the Research Assistant conducts a Women's Health Interview (baseline).
 - If the participant is randomized to the Not Contact Control Group (NCCG), the Research Assistant concludes with the enrollment process.
 - If participant is randomized to the BIG group, the Research Assistant refers the participant to the MET Therapist after completing IVRS and the Women's Health Interview. Subjects in the Assessed Control Group (ACG) and the No Contact Control Group (NCCG) do not receive the MET session with a counselor.
 - Each MET Therapist carries a study cell phone, so Research Assistants can reach an MET Therapist at all times.
 - MET Therapist cell phone numbers are posted in the study office and on the study computers in the ED.

Supervision

Research Assistants are supervised by an on-site a full-time Research Assistant and Retention Specialist (one at each location), and by the Project Manager, who monitors bi-weekly, monthly and semester screening and enrollment counts, as well as data quality for each individual research assistant on staff. Supervision reports are provided to the principal investigator and co-investigators upon request.

Motivational Enhancement Therapy (MET) Therapists

Overview

The MET Therapists are Masters level counselors (with degrees in psychology, social work, or a closely related field). The MET Therapists perform the intervention for the research study.

Training & Supervision

MET Therapists will need access to a study cell phone in order to be contacted by Research Assistants about eligible patients. In addition to the below targeted training and skill sets, MET therapist are provided with a half day overview of the project goals and procedures, as well as documentation requirements and confidentiality issues specific to the sensitive nature of their interaction with clients.

Motivational Interviewing: MET Therapists are trained by a Motivational Interviewing specialist who is a member of the Network of Trainers for two full days. A minimum of three training MET sessions are the conducted by each therapists with ED patients who are not eligible for the larger RCT but meet at least one of the two criteria: Risky Drinking OR Intimate Partner Violence. The recordings of these sessions are then reviewed by the clinical supervisor. Once therapists demonstrate their competence by having 3 or more MET Adherent they are incorporated into the on-call MET schedule and can then provide the MET intervention to participants who are randomized to the brief intervention group. Additionally, MET Therapists receive ongoing clinical supervision from a doctoral-level social worker trained in Motivational Interviewing.

Institutional Review Board: MET Therapists all complete the Human Subjects Training through the IRB before interacting with patients in the Emergency Department.

Intimate Partner Violence: All MET Therapists must have experience working with abused women and/or receive formal domestic violence training (e.g. domestic violence advocate 40-hour training offered through Women Against Abuse).

Supervision

Supervision occurs in both individual and group format. During supervision, recordings of MET sessions are reviewed for adherence to the MET protocol. Any feedback received on 20% of randomly selected recordings by our MET expert consultant is also reviewed. MET Therapists meet weekly or bi-weekly with the clinical supervisor who is a University of Pennsylvania faculty and social worker who specializes in Motivational Interviewing. Supervision sessions allow the MET Therapists to process their encounters with patients in the ED. During supervision, recordings of MET sessions are reviewed for adherence to the MET protocol. If a therapist is not adherent in one or more of the sessions reviewed during supervision, they must conduct a 1-3 practice sessions which will be reviewed by the clinical supervisor at the next supervision meeting. One-on-One meetings are held if deemed necessary by the clinical supervisor and principal investigator, until the therapist is fully adherent to MI and is cleared to perform the intervention.

Supervision of documentation and scheduling is managed by the Project Manager.

Tasks/ Job Responsibilities

1. The primary role of an MET Therapist is to provide Motivational Enhancement Therapy to all participants who are randomized into the Brief Intervention Group. Participants randomized into the NCCG and ACG groups are also offered MET at the completion of the study.
2. In addition, MET Therapists provide a 10 to 20 minute “booster session” to BIG participants. This is a follow-up phone call to reinforce those topics covered during the original MET session. MET Therapists call the participant using “safe contact information”, which is collected at the time of enrollment.
3. MET Therapists are scheduled using an on-call schedule. They are provided with a study cell phone, and during “on-call” shifts the Research Assistant will contact them if they enroll a participant who is randomized to receive the brief intervention (BIG). MET Therapists need to arrive at HUP or PMC within 1 hour of receiving the call, which is the estimated time to complete all other enrollment activities prior to intervention.
4. Documentation: MET Therapists are responsible for uploading and saving their recordings to a secure drive, and securely sending them to the clinical supervisor and project manager. In addition, MET Therapist must document all attempted contacts with participants to schedule the “booster session.” If the booster session is completed or if the allotted 11 weeks or 10 contacts have been made with no success, MET therapist must submit a completed MET Booster Form indicating the length and topics covered in the “booster session.”

Section 4 Study Procedures

The following steps present an abbreviated procedural process for recruitment, enrollment/randomization and the study activities for each of the three groups.

Approach & Screen

1. Screeners access the Social Health Bin in EMTRAC to determine all female patients ages 18-64 currently in the Emergency Department.
2. Screeners distribute and review Social Health Surveys from the present female patients ages 18-64.
3. If a patient screens positive for IPV Risk or Alcohol Risk on the Social Health Survey (specific questions), the screener notifies a senior research assistant (RA).
4. The RA is introduced to the patient and administers the Eligibility Assessment (CTS2S & AUDIT) to determine study eligibility.
5. Patients not interested or not eligible will be thanked for their time and reminded to give the Social Health Survey to the doctor or nurse caring for them. Any serious risks, including: IPV-only or Alcohol-only will be brought, with the patient’s permission, to the attention of the physician.

Re-Approaching Patients

On occasion a patient is not able and/or willing to complete a SHS at the time they are first approached. Patients can be re-approached in the following manner under the following circumstances:

1. If a patient reports too much pain/too sick:
 - Offer to verbally administer the SHS.
 - Allow the patient a brief amount of time in hopes that she will eventually experience less pain and illness (within 60 minutes).
2. If a patient is receiving medical care:
 - Wait outside of the patient's room for the health care professional to finish providing care.
 - Approach patient at a later time (try back within 10 minutes).
3. If a patient is sleeping:
 - If the patient cannot be aroused by opening the room door and/or gently calling their name, approach them at a later time (within 30 minutes).
4. If it is not an appropriate time to approach a patient (see Section 4.3.2.4 Code definitions for the not appropriate time codes):
 - Monitor the patient's room to establish an appropriate time and re-approach the patient.
5. If a patient is under the influence of medication, drugs or alcohol:
 - Wait 60 minutes and re-approach patient.
 - Patient must be sober to engage in the research study.

Screening Questions

Patients complete their Social Health Survey (SHS – Appendix A) on their own (or verbally administered by the RA if more convenient for the participant), and then the RA reviews completed SHSs quietly and discreetly.

Risky Drinking Behavior identified by:

- Question 7 – Response greater than or equal to '1'
- Question 8 & 9 – Multiplied Responses (drinking days X typical number of drinks) is greater than or equal to '7'.

Potential IPV identified by:

- Question 22 through 27 – Response of 'Yes' to any one of these questions
- Question 30 – Response of 'Yes'

NOTE: IF patient indicates 'Not Sure' for any of the IPV questions, further probing may be warranted to determine if positive for IPV Risk.

Patient with positive screen declines further assessment

If the patient screens positive for either SHS #18 or SHS #26 for CURRENT fear/threat (from anyone) or for CURRENT depression (in the last two weeks), it is important that the level 2 Research Assistant ask permission to notify the treating provider: Thank you for sharing that you are "feeling threatened" /"feeling depressed" This can have a huge impact on your health! Would you like for me to bring this to the attention of the doctor taking care of you? – or would you rather do that yourself?

If the patient says NO – or that they would rather be the one to share this information – leave the Social Health Survey in the room for the doctor to review as part of routine care. Make sure you tear off and give the patient the resource guide – pointing out the appropriate resources!

If the patient agrees to let you share the information, find the treating resident or attending. Provide them with the SHS, pointing out the concerning risk factor(s) and let the provider know that referrals have been provided but it is our protocol to let the provider know about any current IPV or severe depression, with the permission of the patient.

Assess

Research Assistants will assess a patient's eligibility by verbally administering the CTS2S and AUDIT. To expedite the enrollment process, the Research Assistant should carry copies of the Eligibility Assessment, when screening patients.

Please remember no family members/partners/children can be in the room while administering the eligibility assessment. Level Two Research Assistants are expected to ask visitors to please leave the room while the assessment is administered. There are a number of ways this can be done such as, "Before I ask you these questions I will have to ask everyone else to leave the room – this is for privacy reasons and our policy."

Script for Assessment

"I am going to ask you some additional questions about relationships and your health behaviors. Please listen carefully as I go over the possible responses. For each of these statements tell me which response indicates how true these statements are to you and your experiences. Some of these questions may seem like they do not apply to you or that I've asked them already. I ask that you still give me your answer as I have to ask these questions as they appear. So that we can make sure we don't get interrupted I'd like to go straight through these questions and then we will have a chance to discuss them afterwards."

If patients asks for clarification of assessment questions, do NOT provide your interpretation of the question; rather simply state "Whatever that means to you."

Determining Eligibility

Patients must be eligible based on their CTS2S AND AUDIT Score

- Upon administering the CTS2S, any patient who has a score equal or greater than 1 is eligible for study participation.
- Upon administering the AUDIT, any patient who has a score equal or greater than 4 is eligible for study participation.

Consent, Randomize & Enroll

1. If a patient is eligible (CTS2S \geq 1 & AUDIT \geq 4) and they agree to enroll in study, RA consents the patient.
 - a. RAs review the written consent form in detail with the patient, answering any questions they may have about the study. Then obtain their signature on the consent form.
 - b. If patients are interested, but are being discharged from the ED the RA can (1) see if there is room available in the family room or allocated space for study enrollment or follow-up activities, or (2) collect safe contact information and a preferred time to return to the ED and complete enrollment procedures. If the latter RAs should NOT randomize participants.
2. After the individual has consented to participate in the study, they are ready to be enrolled and randomized to a treatment group. The Project Coordinator prepared opaque envelopes that are indistinguishable from each other and thick enough so that their contents are not legible from the outside. Research Assistant should return to the project office and draw the next sequential envelope from the file, beginning with #1001 for the first subject. In addition to the randomization envelope, it will also be helpful to bring the 3 study packets (one for each group), so the enrollment process can begin right after the participant is randomized.
3. Once participants are assigned a group and study ID, the RA should create a casefile for the participant from the appropriate study packet by labeling it with their Study ID. Remember, once started, this file will contain personal information and should not be left unattended. RA should then conduct the correct treatment procedures for their assigned group, which are detailed below.

Treatment Procedures

If patient is randomized to:

No Contact Control Group (NCCG)

1. RA completes the Safe Contact Plan and Personal Information Sheet with the patient (demographic information).
2. Upon completion of the Study Participation Reimbursement Form, the RA provides patient with study reimbursement for agreeing to participant in study.

3. RA informs patient that they will be contacted to complete an assessment in three months using the safe contact information they provided. Patients are provided with a business card with the schedule for the sequential contacts and phone number to reach study staff.
4. Three months later, the RA contacts patient using safe contact information to set up an appointment for patient to complete NCCG Follow-up Women's Health Interview.
5. Upon completion of the Study Participation Reimbursement Form, RA provides patient with study reimbursement for completing the WHI and study completion.
6. Patient's study participant is now completed and they will be offered a MET intervention by a trained MET Therapist.

Assessed Control Group (ACG)

1. Patient completes the Safe Contact Plan and Personal Information Sheet (demographic information).
2. RA administers Baseline Women's Health Interview.
3. RA enrolls patient in Interactive Voice Response System (IVRS) and informs patient how to complete their weekly phone surveys.
4. Patient completes first IVRS call with RA assistance to ensure the process is clear and the enrollment information was accurately captured.
5. Upon completion of the Study Participation Reimbursement Form, the RA provides patient with study reimbursement for study activities completed so far.
6. RA informs patient that they will be contacted to complete an assessment in three months using the safe contact information they provided. Patients are provided with a business card with the schedule for sequential contacts and phone number to reach study staff.
7. Study Staff will monitor completion of the weekly IVRS calls, providing reimbursements wirelessly through an electronic incentive system. If patients miss more than 2 calls in a row, study staff will contact the patient using the safe contact information to remind them to complete the IVRS survey. If patients forget their Study ID or password, or if they lose their card they are instructed to contact the study staff.
8. Three months later, the RA contacts patient using safe contact information to set up an appointment for patient to complete 3-month Follow-up Women's Health Interview.
9. Upon completion of the Study Participation Reimbursement Form, RA provides patient with study reimbursement for completing the 3-month Follow-up WHI.
10. RA informs patient that they will be contacted to complete an assessment in three months using the safe contact information they provided. Patients are provided with a business card with the schedule for the sequential contacts and phone number to reach study staff.
11. Steps 8 through 10 will be completed at the 6-month mark for the completion of the 6-month WHI.
12. Steps 8 & 9 will be completed at the 12-month mark for the completion of the 12-month WHI.
13. Patient's study participant is now completed and they will be offered a MET intervention by a trained MET Therapist.

BIG (Brief Intervention Group)

1. Patient completes the Safe Contact Form and Personal Information Sheet (demographic information).
2. RA administers Baseline Women's Health Interview.
3. RA enrolls patient in Interactive Voice Response System (IVRS) and informs patient how to complete their weekly phone surveys.
4. Patient completes first IVRS call with RA assistance to ensure the process is clear and the enrollment information was accurately captured.
5. RA will contact the MET Therapist and RA provides MET Therapist with patients Social Health Survey and Eligibility Assessments (CTS2S & AUDIT).
6. MET Therapist will conduct a 20-minute audio-taped Motivational Enhancement Therapy session.
7. MET Therapist informs patient that they will contact them in 7-10 days regarding their action plan. MET Therapists will verify the best number to contact the patient, referencing the Safe Contact Plan.
8. Upon completion of the Study Participation Reimbursement Form, the RA provides patient with study reimbursement for study activities completed so far: WHI, IVRS, MET Session.
9. RA informs patient that they will be contacted to complete an assessment in three months using the Safe Contact Form they provided. Patients are provided with a business card with the schedule for sequential contacts and phone number to reach study staff.
10. Study Staff will monitor completion of the weekly IVRS calls, providing reimbursements wirelessly through an electronic incentive system. If patients miss more than 2 calls in a row, study staff will contact the patient using the

Safe Contact Plan to remind them to complete the IVRS survey. If patients forget their Study ID or password, or if they lose their card they are instructed to contact the study staff.

11. Three months later, the RA contacts patient using Safe Contact Plan to set up an appointment for patient to complete 3-month Follow-up Women's Health Interview.
12. Upon completion of the Study Participation Reimbursement Form, RA provides patient with study reimbursement for completing the 3-month Follow-up WHI.
13. RA informs patient that they will be contacted to complete an assessment in three months using the Safe Contact Plan they provided. Patients are provided with a business card with the schedule for the sequential contacts and phone number to reach study staff.
14. Steps 8 through 10 will be completed at the 6-month mark for the completion of the 6-month WHI.
15. Steps 8 & 9 will be completed at the 12-month mark for the completion of the 12-month WHI.

Section 5 Data Collection Tools & Methods

Engagement and Study Completion (Coding for CONSORT)

The Screener's Tracking Form is used to track specific information, about every patient in the electronic Social Health Bin during data collection timeframes. This information provides a summary of each patient's engagement with the research study. Each Screener should fully complete the appropriate tracking information on the paper form and then electronically document this information by completing the Social Health Bin Data Entry Screen (Section 4.2.2.3 Data Entry Process). It is important to track all patients in the ED during data collection timeframes in the Social Health Bin; the Screener's Tracking Form should be seen as an administrative tool to ensure accurate and efficient documentation in the Bin. Once all data has been updated in the Social Health Bin all forms should be placed in the hanging file folders organized by month in the designated cabinet.

Tracking Engagement and Reasons Why Not Tracked

If patients do not complete a certain level of engagement, research assistants track the reason why they did not proceed using certain codes. In other words, once a research assistant enters No ("N") for a specific engagement level and they then use the following codes under "If no, why?" Once this code is entered, the research assistant does not need to complete any other engagement elements located to the right on the Screener's Tracking Form. It is important that all information is completed in its entirety and accurately reflects the final engagement level and completed study activities. This information is used to electronically document tracking information in the Social Health Bin.

Approach (Y/N): Indicate if screener approached patient using "Y" for Yes and "N" for No

If no, why?(code): If screener did not approach patient please use ONE of the following codes (also in the key on the bottom of the tracking sheet) to indicate why patient was not approached:

- (NA-F) Family/Others present
- (NA-M) Receiving medical care
- (NA-S) Sleeping
- (NA-D) Under the influence of med, drug, or alcohol
- (NA-E) Severe Emotional/Psychological Distress
- (P) Physical Illness/Physically unable/Pain
- (CI) Cognitive Impairment / Psychosis
- (SH) Suicidal / Homicidal Ideation
- (ND) Not English-speaking
- (J) Incarcerated/Arrested
- (A) Admitted
- (DC) Discharged / Has left the ED
- (O) Other

Screen w/ SHS (Y/N): Indicate if screener reviewed the patient's completed Green Social Health Survey (SHS) for Risky Drinking (Q 7-9) and Partner Violence (Q22-27 & 33).

If no, why? (code): If screener did not review/screen the patient with the SHS please use ONE of the following codes (also in the key on the bottom of the tracking sheet) to indicate why patient was not Screened with the SHS:

- (NA-F) Family/Others present
- (NA-M) Receiving medical care
- (NA-S) Sleeping
- (NA-D) Under the influence of med, drug, or alcohol
- (NA-E) Severe Emotional/Psychological Distress
- (P) Physical Illness/Physically unable/Pain
- (CI) Cognitive Impairment / Psychosis
- (SH) Suicidal / Homicidal Ideation
- (ND) Not English-speaking
- (J) Incarcerated/Arrested
- (A) Admitted
- (DC) Discharged / Has left the ED
- (D) Declined
- (O) Other

SHS (+/-): If patient was screened with the SHS for Risky Drinking and Partner Violence (i.e. Screen w/ SHS = Y), please use a positive "+" and negative "-" symbols to indicate if they were positive or negative for both IPV and Alcohol.

IPV: Positive "+" should be indicated if a patient answers yes to any one of questions #22-27 or 30.

Alcohol: Positive "+" should be indicated if a patient consumes more than 4 alcoholic drink on any occasion (>0 on question #7), or more than >7 drinks per week (calculate using question 8&9)

**NOTE: A patient should be proceeding to the next level of engagement "Assessed" if they are screened. If a patient is negative for Alcohol & IPV, Assessed=N and Reason=SCR – No further assessment based on screener. If positive for either IPV or Alcohol and will to be assessed, administer Eligibility Assessment. **

Assessed (Y/N): Indicate if patient is assessed by the Research Assistant with the Eligibility Assessment (CTS2S & AUDIT)

If no, why? (code): If the patient was not assessed with the Eligibility Assessment please use ONE of the following codes (also in the key on the bottom of the tracking sheet) to indicate why patient was not assessed:

- (NA-F) Family/Others present
- (NA-M) Receiving medical care
- (NA-S) Sleeping
- (NA-D) Under the influence of med, drug, or alcohol
- (NA-E) Severe Emotional/Psychological Distress
- (P) Physical Illness/Physically unable/Pain
- (CI) Cognitive Impairment / Psychosis
- (SH) Suicidal / Homicidal Ideation
- (ND) Not English-speaking
- (J) Incarcerated/Arrested
- (A) Admitted
- (DC) Discharged / Has left the ED
- (D) Declined
- (O) Other
- (SCR) No further assessment based on screener

Eligibility Assess Scores: If patient was assessed with Eligibility Assessment, please calculate and write in their CTS2S and AUDIT Scores (regardless of if they are eligibility for the study or not).

CTS2S: A calculated CTS2S Score will be a numeric value between 0 and 96.

AUDIT: A calculated AUDIT Score will be a numeric value between 0 and 40.

Eligible(Y/N): Indicate if patient is eligible for the study based on their Eligibility Assessment Scores.

*NOTE: A patient is Eligible for the study with CTS2S Score \geq 1 **AND** an AUDIT Score \geq 4*

Enrolled (Y/N/C): Indicate if patient consents and enrolls in the study. Using the following codes: Y=Yes, N=No, C= Need to Contact/Safe Contact collected

If no, why? (code): If patient is not enrolled in the study please use ONE of the following codes (also in the key on the bottom of the tracking sheet) to indicate why patient is not consented and enrolled.

- (CI) Cognitive Impairment / Psychosis
- (MU) Medically (Physical/Emotional) Unable to Participate
- (SH) Suicidal or Homicidal Ideation
- (J) Arrested / Incarcerated
- (PE) Previously Enrolled in Study
- (NI) Not Interested
- (UC) Unable to Contact
- (SC) Safety Concern
- (O) Other (Note Reason): Be sure to take note of the other reason the patient is not enrolled as this information should be entered into the Social Health Bin Data entry screen.

If yes, Assign Study ID: If patient is enrolled, assign patient a Study ID (following Randomization procedures) and indicate it in this column. This information will not be entered into the Social Health Bin, but it is important it is documented on the paper form for tracking purposes.

NOTE: The Eligibility Assessment forms are kept for ALL assessed patients

- *If a patient is not eligible, please remove all identifying information and place in the "Assessed, Not Eligible" folder in the designated filing cabinet*

- *If a patient is eligible, but not interested in enrolling in the study, please write a brief description as to why they are not interested, remove all identifying information, and place in the "Eligible, Not Enrolled" folder in the designated filing cabinet.*

- *If a patient must leave, but will be contacted possible future enrollment, keep the form and indicate the patient's encounter number on the form (which will be removed if the patient does not enroll in the study. Their assigned Study ID should only be written on top of the Eligibility Assessment, at the point that they are consented, randomized and formally enrolled in a study group.*

- *NO IDENTIFYING INFORMATION should be written on the Eligibility Assessment for patients who do not enroll in the study.*

Table of Tools and Forms

Data Collection Tool	Completed by	Description	Collection Protocol
Social Health Survey	All patients registered in the ED	Allows patient disclosure of psychosocial risks and preliminary identification of IPV risk.	Ongoing; screens for potential eligibility for intervention/study; May be distributed by ED registrations staff (part of routine care) or by Study Screeners (Level 1 & 2). Reviewed by Study Screeners (Level 1). Please leave SHS in room for the health care team's use.
Screener's Tracking Form	Level 1 & 2	Tracks specific information for every patient – female between ages 18-64 – registered in the ED during data collection timeframes. Includes elements tracking patient engagement with the research study.	On-going; monitors daily accountability of Level 1 & 2; Paper trail of patient engagement data; Should be stored systematically in project office; See Directions for Screener's Tracking form for completions instructions.
Social Health Bin (EMTRAC)	Level 1 & 2	Displays female patients ages 18 -64 who are currently in the ED (available for screening); Bin Form tracks selected elements from the Screener's Tracking Form	Daily; Electronically captures data collected on Screener's Tracking Forms in EMTRAC; Level 1 & 2 update bin during shift. Level 2 RAs update to reflect assessment and enrollment activities.
Eligibility Assessment Form	Level 2 RAs	Determine eligibility for study using CTS2S (abusive behavior scale) and AUDIT (drinking scale) Assessments; Patients are eligible if they CTS2S = 1 or more AND AUDIT = 4 or more.	Administered by Level 2 RAs; For all assessed patients, Eligibility Assessment Scores (CTS2S & AUDIT) should be tracked on Screener's Tracking Form & in Social Health Bin; If Not Enrolled, the Eligibility Assessment Form should be destroyed. If Enrolled, Study ID should be assigned and written on Eligibility Assessment Form and placed in casefile.
IRB Approved Study Consent Form	Level 2 RAs	IRB Approved Study Consent and HIPAA Authorization Form.	Administered by Level 2 RAs; Reviewed with and signed by eligible participants who wish to enroll in the study; Copy of signed consent form placed in casefile; Originals collected by Project Coordinator and stored in administrative offices for IRB Audit.
Individualized Safe Contact Plan	Level 2 RAs	Collects Safe Contact Information from all study participants regardless of assigned study group.	Administered by Level 2 RAs; Collect accurate contact information that ensure safety of participant; Completed form to be placed in casefile and referenced for all participant contact.

Data Collection Tool	Completed by	Description	Collection Protocol
Participant Demographics Sheet	Level 2 RAs	Collects Personal Information (Demographics) from <u>all</u> study participants regardless of assigned study group.	Administered by Level 2 RAs; Medical Record Number, Encounter Number & date of birth should be recorded; Randomization process occurs prior to completion; Completed form to be placed in casefile.
ACG & BIG Baseline Women's Health Interview	Level 2 RAs	Extensive assessment for ACG & BIG participants; includes scales for primary and secondary outcomes, mediators and moderators as well as additional information.	Administered by Level 2 RAs once patient has consented, enrolled and randomized; administered to ACG & BIG participants only.
ACG & BIG Follow-up Women's Health Interview	Level 2 RAs	Extensive follow-up assessment for ACG & BIG participants completed at 3, 6, & 12 months; includes scales for primary and secondary outcomes, mediators and moderators as well as additional information.	Administered by Level 2 RAs to ACG & BIG participants at 3-months, 6-months & 12-months.
NCCG Follow-up Women's Health Interview	Level 2 RAs	Extensive assessment for NCCG participants completed at 3 months; includes scales for primary and secondary outcomes, mediators and moderators as well as additional information.	Administered by Level 2 RAs to NCCG participants at 3-months.
Timeline Follow Back Worksheet	Level 2 RAs	Form used to collect TLFB data during Baseline and Follow-up Women's Health Interview.	Administered by Level 2 RAs as a part of the Baseline (past 3 months) and Follow-up (past 30 days).
IRB Approved Audio-Taping Consent Form	Level 2 RAs	IRB Approved Audio-Taping Consent for participants who are randomized to the BIG group and receive the MI Intervention.	Administered by Level 2 Research Assistant prior to 20 minute MET intervention; reviewed and signed by eligible participants who are randomized to the BIG group; Copy of signed consent form placed in casefile; Originals collected by Project Coordinator and stored in administrative offices for IRB Audit. If participant does not consent to audio-recording, the consent should not be signed; however, they can still participate in study.
MET Booster Session Form	MET Therapist	Guidelines and data collection form used when conducting the follow-up phone call 7-10 days after BIG participants receive the MET Session by the MET therapist.	Administered by MET Therapist who conducted the initial MET session; BIG participants receive a follow-up phone call 7-10 days after initial session; MET Therapist should also take brief notes on each participant if it appears that she is likely to drop out of the study.

Data Collection Tool	Completed by	Description	Collection Protocol
Study Participation Log	Level 2 RAs; MET Therapist	Detailed "cover sheet" for all study participants; Tracks completed documentation (by group assignment), closure status, and loss-to follow-up.	Initiated by Level 2 RAs; Updated throughout study to track participant engagement by Level 2 RA and MET Therapist; Log linked to NIAAA Participation Database.
Attempted Contact Log	Level 2 RAs / MET Therapists	Form to document all attempted contacts for every enrolled participant. Form can also be used to document attempted contacts with eligible but not yet enrolled participants.	Initiated by Level 2 RAs at enrollment; Updated throughout study to track on-going contacts with participant; Attempted contacts should also be tracked in the Participation Database
Study Participant Reimbursement Registration Form	Level 2 RAs or MET Therapist	Form to document amount of incentive, reason and signature of participant, in compliance with UPenn/SP2 Accounts Payable Policy.	Form completed by participant to register PNC reloadable incentive card; Signature indicates that payment will be electronically made to participant for completed activities throughout study enrollment.
Adverse Event / Protocol Violation Documentation	Level 2 RAs or MET Therapist	Form to document all adverse events and protocol violations. Includes date of event, time of event, related study ID number, and space for a qualitative description of the event.	Form completed by any member of staff as soon as event occurs. The original forms should be immediately provided to the project manager and a copy should be placed in the participants file.

Table of Measures (Assessment Battery)

Variable	Construct	Measure	Measure Ref.	# items	Sample Item	Response Type
Primary Outcomes	IPV Frequency	CTS2S	Straus & Douglas [23]	16	# times partner hit, punched, or beat up.	# incidents
	Heavy Episodic Drinking	AUDIT/ AUDIT-C	Reinert [22] Bush [37]	3	How often do you have 4+ drinks on one occasion?	# heavy drinking days
Secondary Outcomes	IPV Severity (past wk.) ·Victim ·Perpetrator	CTS2S	Straus & Douglas [23]	6	#times partner used force to have sex.	#categorized as "severe"
		Compositive Abuse Scale (CAS)	Hegarty et al. [36]	30	How many times in the past 3 months have the following things happened to you: - Told me that I was ugly. -Tried to keep me from seeing or talking to my family.	Likert (0-5)
	Alcohol quantity/ frequency (past wk.)	AUDIT-C	Bush [37]	3	In the past week, how many days have you had a drink containing alcohol?	#days/week X #drinks/day
		Timeline Followback	Sobell & Sobell [35]	28 days	Please indicate the number of drinks you had on each day for the past month (28days)	Calendar documentati on of number of drinks
	Self-Rated Health		Andresen et al. [46]	1	How would you say your health has been?	Likert (1-5)
	Health Behaviors ·Smoking ·Exercise	GENACIS (5 selected items)	Wilsnack & Wilsnack [47]	2	How many days/week do you engage in vigorous physical exercise?	#cigarettes #days exercise
	Quality of Life	WHOQOL Qs (3 selected items)	WHO [48]	3	How much do you enjoy life?	Likert (1-5)
	Relationship Satisfaction	Dyadic Adjust. Scale	Hunsley et al. [49]	1	Which response best describes the happiness in your relationship?	Likert (0-6)

Table of Measures (Assessment Battery)

Variable	Construct	Measure	Measure Ref.	# items	Sample Item	Response Type
Mediators						
Personal Changes	Self-Efficacy	Generalized Self Efficacy Scale	Schwarzer [50]	10	I can always manage to solve difficult problems if I try hard enough.	Likert (1-4)
	Motivation to Change importance/ confidence for alcohol/IPV	Importance/ Confidence Rulers	D'Onofrio et al. [51]	4	On a scale of 1-10, how important is it to you to take steps to change the conflict in your relationship?	Likert (1-10)
	Self-help actions	Steps to Safety		1	Have you taken any steps in the past 3 months to increase your safety?	Yes/No If Yes, Describe (qual.)
Social/ Community	Social Support	Social Support Network Scale	Block [52]	3	Do you have someone you could stay with if needed?	Yes/No Score 0-3
	Engagement with: ·Criminal/Civil Court ·IPV agencies ·Alcohol peer support			3	Have you used any police or court services because of family violence?	Yes/No
Engagement in Treatment	Outpatient/Inpatient: ·Alcohol ·Drug ·Mental Health ·Healthcare ·Significant Family Problems			9	How many times have you seen a health professional on an outpatient basis for problems with alcohol?	# treatment visits
Moderators						
	IPV Severity at Baseline (low/high)	Women's Experience with Battering Scale	Smith et al. [39]	10	I feel like he keeps me prisoner.	Likert (1-6) Score 10-60
	IPV Severity at Baseline (low/high)	Danger Assessment	Campbell [38]	20	Does he own a gun?	Yes/No Weighted score
	Likely Alcohol Dependence	AUDIT Qs 4,5, 6	Reinert [22]	3	How often have you needed a first drink in the morning to get going?	Likert (0-4) + or - for dependence

Table of Measures (Assessment Battery)

Variable	Construct	Measure	Measure Ref.	# items	Sample Item	Response Type
Moderators (cont)	Illicit Drug Use	GENACIS (4 selected items)	Wilsnack & Wilsnack [47]	3	In the past 3 months have you used marijuana? street drugs? Misuse Rx drugs?	Yes/No & Frequency
	Depression	CES-D10	Radloff [53] Andersen et al. [54]	10	I was bothered by things that don't usually bother me.	Likert (0-3) Score 0-30 (11+ = depression)
	PTSD	Primary Care PTSD Screen	Prins et al. [55]	4	Have you had an experience that was so upsetting that you have had nightmares about it?	Yes/No Score 1-4 (Score 3+=PTSD)
	Sexual Abuse History	GENACIS (2 edited items)	Wilsnack & Wilsnack [47]	2	Before you were 16 years old did someone try to make you do/watch sexual things?	Yes/No
	Partner Drinking	GENACIS	Wilsnack & Wilsnack [47]	6	When you and your partner quarrel, how often has your partner been drinking?	Likert (1-5) All the time/Most times...

Section 6 Planned Statistical Analyses

Primary Analysis: Heavy Drinking Outcomes

For the heavy drinking primary measure, our primary analytic method will be hierarchical linear models (HLM; also known as random coefficient models and multilevel linear models) (Bryk & Raudenbush, 1992; Goldstein, 1995) applied to the 12 weekly IVR assessments of heavy drinking episodes, comparing the motivational intervention to the assessed control group. The HLM approach will account for the clustered structure of the data (i.e., repeated weekly assessments within subject). The HLM framework also offers flexibility for the nature of the outcomes. For count measures (i.e. number of days of heavy drinking the past week) a special class of HLM, Hierarchical generalized linear models (HGLM), will be implemented. HGLM extend HLM analogously to how Generalized Linear Models extend the General Linear Model structure by including a link function relating the mean and variance to the nature of the specific outcome. We will implement the HGLM model with the SAS Procedure GLIMMIX on the count outcome using Mixed effects Poisson Models for count outcomes. In the presence of a large proportion of data stacked at one response such as zero, corresponding to no occurrence of the specified event, no transformation can successfully normalize this stack of common responses. If this occurs we will implement zero-inflated Poisson (ZIP) and zero-inflated Negative Binomial (ZINB) regressions which model the stack of zeroes in the structural portion of the model. ZIP and ZINB models are mixture models in which the complete distribution of the outcome is approximated by mixing two component distributions (Atkins & Gallop, 2007). The most common approach is to assume a logistic regression model for the “zero, not zero” aspect of the outcome and either a Poisson or Negative Binomial distribution for the count portions of the model (Lambert, 1992). ZIP and ZINB models with random effects, will accommodate the clustering present in the repeated assessments (Lee, 2006).

Benefits of HLM/HGLM include (1) the ability to inspect if the results are biased due to drop out or missing data, (2) the use of all available data from each participant, making this analysis a full intent-to-treat (ITT) analysis, and (3) flexibility with the treatment of time. The basic formation of the HLM/HGLM considers time as linear. If one does not expect the outcome to change across time in a linear fashion, then a refinement of the model is possible. Empirical evidence is accumulating that change during interventions may be non-linear. More precise models of change may elucidate unique clinical characteristics of different treatments and may identify possible mechanisms of change. One could model time as linear, piecewise, quadratic, cubic, log-linear with respect to time, or square-root transformation of time to reflect the nature of change over time. With our goal to truly model the nature of time, we will generate the average profiles per group. These plots will provide the starting point to describing the change over time mathematically. The mathematical complexity will be balanced between the number of repeated assessments and clinical interpretation.

For our proposed study, modeling the pattern of change over time will be guided by the following. A number of studies of alcohol and/or substance abuse treatment have shown a pattern of change over the course of treatment in which patients (regardless of intervention or control) reduce alcohol/drug use over the first month following elevated levels at baseline (Ball, 2007; Sommers, 2006; D'Onofrio, 2008). The effect of intervention is then seen beyond one month as patients have slips and relapses up to about 3 months. Outcomes after 3 months are then relatively stable (or slightly worse) through 6 to 12 month follow-up. For example, in the Ball (2007) study, alcohol and substance use decreased from baseline levels to near zero by one month in both the motivational enhancement (MET) and treatment as usual groups. However, significant treatment differences emerged from week 4 to week 12, with the MET group showing less increase in use (slips; relapses) than treatment as usual. We expect the same pattern of change to be evident in this proposed study.

Likelihood estimation as performed with HLM/HGLM is especially robust to missing data compared to other procedures such as Generalized Estimating Equations or weighted least squares regression. Of course, the model assumptions are more stringent under likelihood estimation and need to be assessed with procedures such as residual analyses and sensitivity analyses. However, when the missing data is informative (i.e., dependent on the outcomes that would have been observed had they not been missing), the hierarchical regression model approaches are thought to produce biased estimates (Diggle, 2002). Nonetheless, Ten Have (1998) provided evidence that treatment group comparisons may not be biased even in the presence of informative missing data with hierarchical regression analyses. To assess the sensitivity of treatment effect estimates to missing data, we propose to fit the hierarchical regression models without accounting for informative missing data, and then compare these results with those from analyses that adjust for informative missing data. We will employ the pattern-mixture approach as applied to hierarchical regression models by Hedeker and Gibbons (1997). Their methods assess whether important terms in the models (e.g., the treatment by linear time interaction) depend on certain missing data patterns, and provide equations to obtain unbiased estimates by averaging over the various missing data patterns. As described by Hedeker and Gibbons (1997), these mixed models allow us to assess

whether important estimates (e.g., average heavy drinking occurrence per Groups) are dependent on missing data patterns, and provide overall estimates of effects by averaging over the various missing-data patterns. In addition, we will consider the extension of the Pattern-Mixture models as described by Guo, Ratcliffe, and Ten Have (2004) which includes the incorporation of random effects in the Pattern mixture model, which allow subject-to-subject heterogeneity.

Power for Analysis of Heavy Drinking Days

Based on previous studies (Blow, 2006; D'Onofrio, 2008), we consider a relative reduction of 2 or more (or ~35% reduction) in heavy drinking episodes/month is a clinically significant outcome. Blow (2006) and D'Onofrio (2008) suggest that rates of heavy drinking will be about 6.0 days/month (SD=6.0) at baseline and end at about 3.5 days/month (SD=5.0) at week 12 for interventions without a special motivational interviewing intervention that targets IPV and focuses on women only. The current study is therefore powered to detect a rate of change over weeks 4 to 12 in the brief intervention group (BIG) that will end with a 2 days/month improvement over the assessed control group (ie, 3.5 days per month for the control, 1.5 days/month for BIG). For the power analysis given below, we convert these monthly rates into weekly rates since our dependent variable is measured weekly.

In the proposed study, we will have repeated weekly measures (i.e. repeated observations within subjects) that are correlated (for the intervention and assessed control groups). This correlation has a profound impact on the resulting tests of significance (Kraemer, 1981). When this within subject correlation is properly incorporated, the repeated measures analysis takes full advantage of all information obtained from each subject, thereby greatly increasing statistical power over methods that compare treatments cross-sectionally (Gibbons, 1993). Using the method described by Diggle, Liang, and Zeger (1994), Hedeker, Gibbons, and Waternaux (1999) derive formulas for power estimation of HLM effects such as trend. These formulations offer flexibility in choice of the covariance structure in their extension of Diggle, Liang, and Zeger (1994). An auto-regressive (AR) covariance structure assumption is incorporated, which assumes points closer in time are more correlated than points further spaced in time. Implementing these formulas, power calculations can be made for repeated measures designs under specified assumptions. In our calculations, we assume an autoregressive covariance structure with a within subject correlation of 0.6. The 0.6 assumption is comparable to what was seen with the Ball (2007) study, where the average within subject correlation was 0.57. Converting the estimates above to weeks instead of months, by simply dividing the estimates by 4, assuming the effect seen in Ball (2007) during the first month of treatment, we anticipate slope estimates per week during the second two months to be 0.109 and 0.046, respectively for the control and BIG groups, with standard deviation over the second two months increasing proportionally from SD=0 at week 4 to SD=1.25 at week 12. We assume a Type-I error level (alpha-level) of 0.025 (splitting alpha between the two primary outcomes of heavy drinking days and IPV incidents) with as most 15% missing outcome data during the first three months. Using the Hedeker, Gibbons, and Waternaux (1999) formulas, with the parameters specified above, we derive a sample size of 176 per group to achieve at least 80% power to detect a significant effect in the rate of change between groups during the second two months of treatment. If attrition/missing data is as high as 30%, we derive a sample size of 199 per group to achieve at least 80% power to detect a significant effect in the rate of change between groups during the second two months of treatment. Thus, with our pre-attrition target sample of 240 subjects per group, we are sufficiently powered to detect our clinically meaningful effect for the differential rate of change between the intervention and assessed control groups during the second two months of weekly treatment, even with attrition/missing data as high as 30% during the first 12 weeks of treatment.

Primary Analysis: Incidence of Intimate Partner Violence (IPV)

Our primary analytic method parallels our approach above, where we will implement HGLM models to accommodate the clustering of the weekly repeated measures, as well as the nature of the outcome, which counts the number of incidences of IPV per week. The HGLM implemented will be a Mixed effects Poisson Models for this count outcome. As described above, in the presence of a large proportion of zeroes, we will implement zero-inflated Poisson (ZIP) and zero-inflated Negative Binomial (ZINB) models with random effects, which accommodate the clustering as well as the stack of zeroes present across the repeated assessments (Lee, 2006).

Power for Analysis Intimate partner violence

Unlike the reduction rates for heavy drinking days per week, there are no prior studies to provide a description of how incidence of IPV will change across 12 weeks. During the 12 week period, we expect the usual care assessed control group to have a 50% incidence of IPV. We consider a decrease of 20% by endpoint to be

clinically significant; therefore, we base our power calculations on a 20% difference between groups in incidence rate of IPV. With an alpha-level of 0.025, a 2-tailed test, with the proposed sample size of 240 per group, the study will have power of 97% to yield a clinically significant result with 15% attrition/missing data across the 12 weeks; and 93.7% to yield a clinically significant result with 30% attrition/missing data across 12 weeks. With our target sample of 240 subjects per group, we are sufficiently powered to detect a clinically meaningful effect between the intervention and assessed control groups even with attrition/missing data as high as 30% during the first 12 weeks of treatment.

Secondary analyses of outcomes

Secondary alcohol use efficacy measures will be analyzed in the same manner as the longitudinal analysis of the primary measure. For secondary efficacy measures collected at baseline, 3, 6, and 12 months, HLM models specifying a linear trend over time will be implemented to compare the intervention and assessed control groups. Covariates will be included as above.

No Contact Control Group

This control group only has eligibility confirmed at baseline and outcome assessment at 3 months. In previous research, assessed control groups show considerable improvement over time (Monti, 1999; Longabaugh, 2001), leading many alcohol researchers to conclude multiple assessments that include questions about the negative effects of alcohol may in themselves constitute an intervention leading to spontaneous motivations to change self-reported drinking patterns (e.g., assessment reactivity, Mundt, 1995). The no contact control group allows us to separate out the extent to which improvements over time in the intervention and assessed control groups may have been due to repeated assessments and personal contact with assessors. Analyses using this control group will consist of analysis of covariance with the 3 month scores as the dependent variable and the corresponding baseline score as covariate. All three groups (intervention, assessed control, no contact control) are included in the analysis, with specific contrasts planned to compare (1) the intervention group to the no contact group, and (2) the assessed control group to the no contact group. Power analyses for these comparisons are based on mean differences at 3 months. With 120 patients in the no contact control group, and 240 in the comparison group, power (2-tailed; $\alpha = .05$) is 80% to detect an effect size (Cohen's d) of 0.33 with up to 30% attrition (84 vs. 168 patients).

Predictor analyses

The HLM/HGLM allows for the inclusion of covariates. Potential predictors will be entered in the model as main effects, as well as potential interaction effects with treatment (intervention group vs. assessed control group) to test for moderation (see next section). Predictor analysis will focus especially on baseline IPV severity and severity of alcohol use. Severe drinking will be defined as more than 21 drinks/week or more than 5 heavy drinking episodes in the last month. Severe IPV will be defined as IPV requiring medical attention (i.e. IPV is the reason for the visit). We will also explore other plausible confounders and predictors identified in the literature including: partner's drinking, use of illicit drugs, depression, PTSD, history of sexual abuse/assault as child and/or adult, directionality and mutuality of IPV, and ethnicity.

Moderation analyses

A moderator is a baseline measure or prerandomization characteristic that has a differential effect on outcome across intervention condition (Kraemer, 2002). Moderators are typically defined as variables that significantly interact with condition (Baron & Kenny, 1986; Holmbeck, 1997). Because the proposed moderators (same variables as given above as predictors) are present before randomization, they should be uncorrelated with intervention assignment (Kazdin & Weisz, 1998). Therefore, we will first test the association between each proposed moderator and intervention assignment (intervention vs. assessed control). Assessment of moderation will be made by augmenting our outcome analyses to include the interaction of the effect of intervention with the moderator. Separately for each potential moderator, we will add the effect of the moderator variable to the model and include the moderator x treatment group (intervention vs. assessed control) interaction. The variable will be considered a significant moderator of the intervention effect if the interaction term is significant (Kraemer, 2002). Statistically significant interactions will be interpreted by plotting simple regression lines for each level of categorical variables or for high and low values of continuous variables (Holmbeck, 1997; Aiken & West, 1991). Cohen's (1988) power tables provide guidance on the estimation of power for the above analyses. Assuming that the moderator variables are measured without error, we need a sample size of 55 to have 80% power to detect a medium effect with an alpha of 0.05. To detect a large effect, we need sample size of 26. While

demographic variables are measured without error, the baseline risk status variables have reliability indices closer to 0.90. Aiken and West (1991) argue that the sample size required to reach a power of 80% with an alpha value of 0.05 is slightly more than doubled when reliabilities drop from 1.0 to 0.80. According to these standards, our sample size of 240 (accounting for 15% attrition) is more than sufficient to detect a medium effect size for a moderator.

Mediator analyses

We hypothesize that factors such as personal changes, social/community factors, and engagement in treatment, will mediate the effects of the intervention. To test for mediation, we will implement the path analysis method described by Baron and Kenny (1986) and extended by Krull and MacKinnon (2001) for repeated measures under the HLM/HGLM framework. Mediation occurs when, after partialing out the mediator, the relationship between treatment condition (intervention group vs. assessed control) and the outcome (i.e., IPV incidents; heavy drinking days) is significantly reduced (in complete mediation the relationship is reduced to zero). The regression analyses, implemented under the Krull-MacKinnon models, can be extended to the modeling approach described for the primary aims. The mediation effect is derived from a function of regression coefficients based on the model corresponding to the path analysis method. Shrout and Bolger (2002) recommend the use of bootstrap methods to obtain better power for the mediation effect, which we will also apply. Bootstrap applications for the repeated measures data will resample units as the entire cluster of information per subject. This method is referred to as case resampling (Efron & Tibshiran, 1986). In addition to the path analysis method, we will examine causal mediation approaches, as described by MacKinnon, Fairchild and Fritz (2007), which provide an adjustment due to potential unmeasured confounding variables. The analysis team has experience implementing these models (Gallop, 2009; Lynch, 2008). Fritz and MacKinnon (2007) documented sample size requirements to guarantee 80% power under the sequential regression framework (i.e., Baron & Kenny, 1986). Under the assumption of a medium effect for intervention with the mediator and a medium effect for treatment condition (intervention vs. assessed control) on outcome co-varying the mediator, the sample size is 110. Therefore our design consisting of a sample size of 240, with an anticipated dropout rate of 15%, is sufficiently powered to detect of mediation.

Section 7 Protection of Human Subjects

Risk to Participants

Victims and perpetrators of IPV are always at risk of further violence. Subjects are also at risk of emotional distress from disclosing personal information of the type asked in the screening interviews, as well as during medical evaluation, subsequent treatment, and follow up monitoring. Research subjects who are engaging in potentially criminal behavior are also at risk of criminal justice intervention or, if it is known that they are participating in a research study, of having their research records subpoenaed. Patients who self-identify as suicidal, homicidal or child abusers, will be at risk of involuntary confinement, involvement of child protective services, or other protective action. There is also the outside risk of re-identification of research data, as this risk must be considered for any data that is stored on a computer.

Adequacy of Protection from Risks

Recruitment and Informed Consent: Patients will sign written consent forms that includes all of the above risks. The consent document includes information about study activities in each of the three possible group assignments and that this is a study of patient psychosocial risk. Trained staff, supervised by experienced clinicians, will review the consent documents with each patient. In all groups, the research assistant will emphasize that participation is voluntary and the participant may stop at any time if he/ she so chooses. Furthermore, participants will be assured that care will in no way be adversely affected by their choices related to study enrollment.

Protected Health Information: All patients enrolled in the study will specifically sign written informed consent forms giving the investigators permission to access their previous and future protected health information. This information will be used to follow participants and track their healthcare utilization.

Audiotaped brief intervention and booster sessions: Patients receiving the brief intervention will sign a separate consent for audiotaping of the MI brief intervention and booster sessions, should they be randomized to that arm of the study. Audiotapes will be kept in a locked cabinet listed only with the study ID number. Independent written

subject permission will be sought if we want to use an individual audiotape for training or teaching purposes at the conclusion of the study. Otherwise, all audiotapes will be destroyed at the end of data analysis or within 5 years after the conclusion of the study, whichever comes first.

Protection Against Suicidal/Homicidal Risk: Subjects will be excluded from study enrollment and will be appropriately linked to needed psychiatric services if they are clinically judged to be homicidal, suicidal, actively psychotic, intoxicated, or otherwise unable to give informed consent due to a cognitive or mental health issue. If enrolled prior to disclosure, any assessed subjects that screen positive for severe depression or suicidal ideation will be further assessed for suicidal risk. Any subject with homicidal or suicidal risk will be transferred immediately for appropriate psychiatric care. Drs. Rhodes and Crits-Christoph are both familiar with and competent in the process of involuntary commitment, should an individual need this level of psychiatric care. As an emergency physician with a secondary appointment in psychiatry, Dr Rhodes, will take primary responsibility for all safety issues related to the study. In the past, she has committed one partner aggressive research subject who was suicidal, with a very good outcome. The Penn Psychiatric Emergency Evaluation Center is immediately adjacent to the HUP ED and Security is readily available at the HUP ED should it be necessary to engage their assistance in order to accompany a subject to psychiatric emergency services where any needed further assessment and interventions can be delivered. Both HUP and Presbyterian are part of the UPHS and in close proximity, therefore sharing these available resources. If the participant is not at the hospital (e.g. at time of follow-up), participants who disclose severe depression, suicidal ideation, or who become emotionally distressed during the study will be referred immediately to a psychiatrist, who will provide an additional layer of consultation and supervision and, if needed, medication. The clinical research team and data safety monitoring board (DSMB) will review the cases of any enrolled research subjects that are referred or considered for potential psychiatric admission. Any potential serious adverse events related to being a subject in the research study will be reported within 24 hours to the IRB and DSMB chair for review. For further information on documentation and procedures on how suicidal risk will be addressed see section below on Specific Suicidality Procedures.

Protection Against IPV Risk: All participants, regardless of level of risk will receive IPV safety, referral, and resource information. In addition, follow-up interviews and safety monitoring via automated IVRS and, when needed, via personal telephone contact, will be individually tailored to meet the safety needs of the study subjects. If concerns of safety are in question, study protocols will be broken. For example, if a participants' abusive partner arrives during any part of the study, we will discontinue the study at that time. In instances of severe potential for danger, we may need to call the police or involve the PI. If study protocols need to be broken, we will inform participants how to reach us and, if safe, we will collect information for follow-up completion of the study if she chooses to continue participation. Participants will be instructed to call 911 or the domestic violence hotline with any safety concerns. They will also be offered the option to return to the ED and speak with a social worker. All participants will receive a social service resource guide that outlines available supports for IPV and other psychosocial concerns, which will be reviewed with study participants before they leave the ED. Subjects will be informed at the onset that the information they disclose to the physician will be recorded as part of the study. The subjects will be informed verbally and as part of the written consents, that they are free to withdraw from the study at any point.

All screening will be conducted in private and will not be discussed with anyone other than the individual subject, nor will the purpose of the study be discussed in the presence of any other person. Subjects will be assessed independently for IPV severity at baseline, and if needed, protocol will be broken to provide ongoing follow up services and referral to community services for IPV-related advocacy and counseling. All assessed subjects will participate in IVRS safety monitoring assessed weekly for the initial 3 months, and by phone or in person at 3-month study intervals. Note at the end of each call the automated IVRS phone contact system that gives them the option to directly connect to the Philadelphia domestic violence hotline. Subjects will also have a number to reach study staff with non-urgent questions about study participation.

Safety issues will be addressed at the time of enrollment, and on an ongoing basis throughout the study period. Should a subject identify fear of harm or potential safety during telephone contact, contact will be discontinued until another time of the subject's choice. There will be a pre-agreed safe method of re-contact and at the first visit we will establish a code that indicates the researcher should call 911. Furthermore, any such incidents will be recorded and reviewed as potential adverse events related to screening or study participation.

Special Protocols and Training Related to Partner Violence: Subject and research staff safety and confidentiality are our primary concern. Due to the extreme sensitivity of the information obtained, all discussion of research and screening will be done in private. We will repeatedly address and explain confidentiality, identity protection, and other trust/consent issues throughout the study period. Research team leaders (and the staff MI therapists) all have training and expertise in IPV-related issues, including in-depth knowledge of, clinical practice and treatment for, and comprehensive research experience with all IPV-involved subjects. Support staff will be trained using established confidentiality and IPV protocols.

Protection Against Risks During Follow Period: Steps have been taken to ensure risks to patients during the follow-up period are minimized.

1. The informed consent form contains explicit statements that keeping a copy of the consent form could put the patient at risk for IPV. This is because anyone who later saw the patients form would know that the patient was being recruited for a study where she/he would be asked about IPV. A copy of the consent form, which contains the elements of HIPAA, will be given to a patient only if the patient explicitly requests to keep a copy of the form. By informing the patient of the risk associated with keeping a copy of the consent form, and by making it clear that the patient does not need to keep a copy of the consent form, our goal is to minimize the possibility of this risk. We can tell them that they can contact us to get a copy of the consent form, should they desire to have it a later point.
2. The information card given to patients at the completion of the baseline interview will list the telephone number to call in order to participate in an automated IVRS telephone survey, but otherwise will be generic: it will appear to be a general invitation to any ED patient to call The Womens Health Study regarding satisfaction with care.

Research Materials and Maintenance of Data Security: In order to ensure confidentiality, all questionnaires will be filled out in private without partners, friends, or other family members. Any individual identifying information will be removed by the primary data management team when the information is entered into a database. The study and survey data collected during the baseline and subsequent visits and follow up IVRS responses will be kept both physically and electronically secure. All filled out questionnaires will be kept in a locked and secured area in the locked research study office. Subject names will not appear on these forms; anonymous subject ID numbers will appear instead. Likewise, any data entered into a database will not have the patients name on it but will be identified only by an anonymous subject ID number. The key to link the subject ID number to the rest of the study information will be kept by the researchers in a separate locked file cabinet, along with subject consent forms and any paper forms used for initial screening and for subject contact information. This information will specifically be kept locked separate from the rest of the subject information and questionnaire data (mental health and IPV measures) data. Those data will be identified only by the anonymous subject ID numbers. The screening/contact forms will be kept until the follow-up period is complete, after which time the name portions of the forms will be removed and destroyed. No one but the PI and project manager will have access to these files. Any data used for results will only be presented in a de-identified manner in the aggregate. The study involves data collected with protection of confidentiality.

Certificate of Confidentiality: As in her other work, Dr. Rhodes has obtained a Federal Certificate of Confidentiality. In her emergency department (ED) work, she likewise collected extremely sensitive personal information, including information about sexuality, sexual abuse, use of illegal drugs, and experiences with interpersonal violence. In that regard, this project will be similar. There is particular concern that the researchers are able to protect the identities of any victims or perpetrators who enroll for the tracking portion of the study. We recruit in private and do not disclose to anyone outside the research team the identities of those actually participating. The PI, Dr. Rhodes, has previously had a number of Certificates of Confidentiality from the National Institute of Mental health and from the National Institute of Justice for her IPV work. We has obtained a project-specific Certificate of Confidentiality from NIAAA for the current study.

Limitations to Confidentiality: All enrolled patients will be informed verbally and as part of a written consent, that they are free to skip any survey questions or to withdraw from the study at any point. They will be informed that the information they provide will be held in confidence to the extent that the law allows under the Certificate of Confidentiality, but that the exception to this confidentiality is any disclosure of potential for immediate harm of themselves or others, such as active suicidal or homicidal ideation or child abuse. The subjects will be notified prior to participation that if any of these issues are raised, the researchers will take whatever steps are necessary

to protect the subject or others, including bringing risk of harm to the attention of the proper authorities. As an emergency physician who studies violence and aggression, Dr. Rhodes is experienced with assessing this type of risk and committing patients or notifying child protective services or law enforcement when necessary. The same is true for Drs. Crits-Christoph and Sommers. They all have the means to involuntarily commit any research subjects that might be of harm to themselves or others. In her previous work conducting computer screening with over 5000 non-urgent, non-psychotic urban ED patients, Dr. Rhodes has found that while approximately 30% screen positive for being depressed for more than 2 weeks in a row in the last year and 2% disclose current suicidal ideation: they are usually interested in receiving mental health referrals. Only a handful required further evaluation by psychiatry. Dr. Rhodes has only had to involuntarily commit one of her male IPV-involved research subjects who disclosed his suicidal intent and the presence of two loaded guns in his home.

Risks/Benefits Assessment

The risks to study participants as a consequence of participation are minimal. While there is a potential that participants may feel emotional discomfort or distress during the questionnaire or interview process, participants are reminded that they may refuse participation, terminate the questionnaire, interview, or follow-up at any point, or decline to answer any question that makes them feel uncomfortable. All participants will be given referral numbers to community-based domestic violence and alcohol abuse agencies. The intervention will be conducted by trained counselors or social work graduate students, who are equipped to manage any patient distress. Risks to the participant's safety are real, in that this is a population at high risk for violence because members have all been victims or perpetrators of IPV. However, these risks are minimal in this study given the protections of confidentiality. Data collection times and phone numbers to be used at follow-up will be negotiated with individual study participants, and a code will have been established that the participant can use to indicate lack of safety and terminate the phone call. This study holds benefits for the practice and research communities addressing issues of IPV, and may yield more direct benefits for individual participants. This study will provide knowledge that can be used to assist other women in similar situations to those who participate in this study, and to aid in preventing future violence against both men and women.

Individualized Safe Contact

In order to minimize risks to participating patients during the follow-up period, any contact will involve an individualized safe contact plan (arranged by the study staff and the patient) which can be changed at any point, as desired by the patient. At the beginning of any phone follow up this is the first thing that will be asked. If participants return to the HUP or PMC ED during their study enrollment, study staff will check in with them to update their safe contact information. In the instance that a participant is difficult to reach – meaning all phone numbers are disconnected and/or reassigned to a new person and secondary contacts are unable to reach, research staff will review contact information in their medical record to determine if it has been updated in follow-up ED visits. If the phone numbers have been updated since their enrollment, we will contact the participant to determine if they are still interested in participating in the study. Staff will be provided with a script and specific protocol to ensure the safety of our study participants.

Data Safety Monitoring Board

Data Safety Monitoring Board (DSMB): The primary responsibility of the DSMB will be to monitor the progress of the study and recommend modifying the trial or terminating the trial as appropriate. Members of the DSMB are listed below. The committee will be composed of four scientists (listed below) who are independent of the study, three of whom are independent of the investigators institution. The study statisticians (Alexandra Hanlon) will serve as a non-voting member of the DSMB. Prior to the first meeting, the Executive Secretary (Project Manager) will document that the members do not have any conflicts of interest. The PI will be responsible for coordinating activities of the DSMB including: 1) arranging DSMB meetings and communications; 2) identifying and reviewing materials to be presented to the DSMB. The Chair of the DSMB will be recruited from the five voting members by the PI in consultation with the NIAAA Program Officer. The chairperson will be responsible for: 1) developing the meeting agenda; 2) requesting information for the meetings from the PI and the study statistician; 3) overseeing the meetings; 4) verifying that the reports and recommendations prepared by the Executive Secretary are an accurate and complete record of the DSMBs deliberations. Concerns that might dictate modification or termination of the study by the DSMB include participant safety, outcome data (data quality, integrity, intervention efficacy), recruitment, and performance. Well defined stopping rules will be in place to guide expected causes of termination.

Data Safety Monitoring Board Several individuals will specifically serve in the role of a data safety monitoring board. The DSMB will meet 3 months after the start of data collection and every 6 months throughout data collection or more frequently as needed in the first 3 years of the project to provide oversight and suggestions for improving study protocols, study execution, and to identify any potential for harm to study subjects. They will be notified of any incidents of severe IPV or need for emergency psychiatry involvement with study subjects and will be notified of any adverse events, along with the IRB. They will work in concert with the study statistician to review early interim and preliminary data and will have independent authority to stop the study, should they perceive it is causing any potential harm. The DSMB members were all chosen for their expertise in various content areas related to IPV, alcohol and mental health interventions, injury prevention and experience with and understanding of clinical trial research procedures, as well as for their quantitative skills, and understanding of the interactions between complex psychosocial issues and mental health.

Adverse Events and Protocol Violations

Adverse events are defined as unanticipated problems involving risks to study participants or others; or as any untoward medical occurrence that may present itself during the study time period which may or may not have a causal relationship with the treatment.

- Serious adverse events result in any of the following outcomes: death, a life threatening experience, inpatient hospitalization, or a significant disability/incapacity.
- Moderate adverse events are those discomforts severe enough to cause interference with usual activities or requiring treatment by a health care provider. Such events also include the loss of participants from the study for reasons related in any way to a deviation from procedures for ensuring confidentiality.
- Mild adverse events are those events that are easily tolerated signs or symptoms of discomfort; minor irritants that cause no loss of time from normal activities; symptoms that require no medication or a medical evaluation; and transient signs and symptoms.

All Adverse Events and Protocol Violations need to be documented – using the Adverse Event / Protocol Violation Form. This is primarily used to ensure documentation of safety issues potentially resulting from participation in the study. Each documentation sheet should be linked to a specific Study ID to detect recurring events and for reporting purposes.

Ideally, the documentation will occur as soon as the event occurs. The original form should be immediately provided to the project manager, Salem Valentino. A copy of this form should be placed in the participant's file. In the case of an adverse event, research assistants should contact Salem at the time of the event.

Specific Suicidality Procedures

Patients who are determined to be suicidal or homicidal are excluded from participation in the study. However, it is possible these exclusion criteria will not be detected until after the participant is enrolled. If this occurs, this person remains a study participant, unless it becomes unsafe for her to participate.

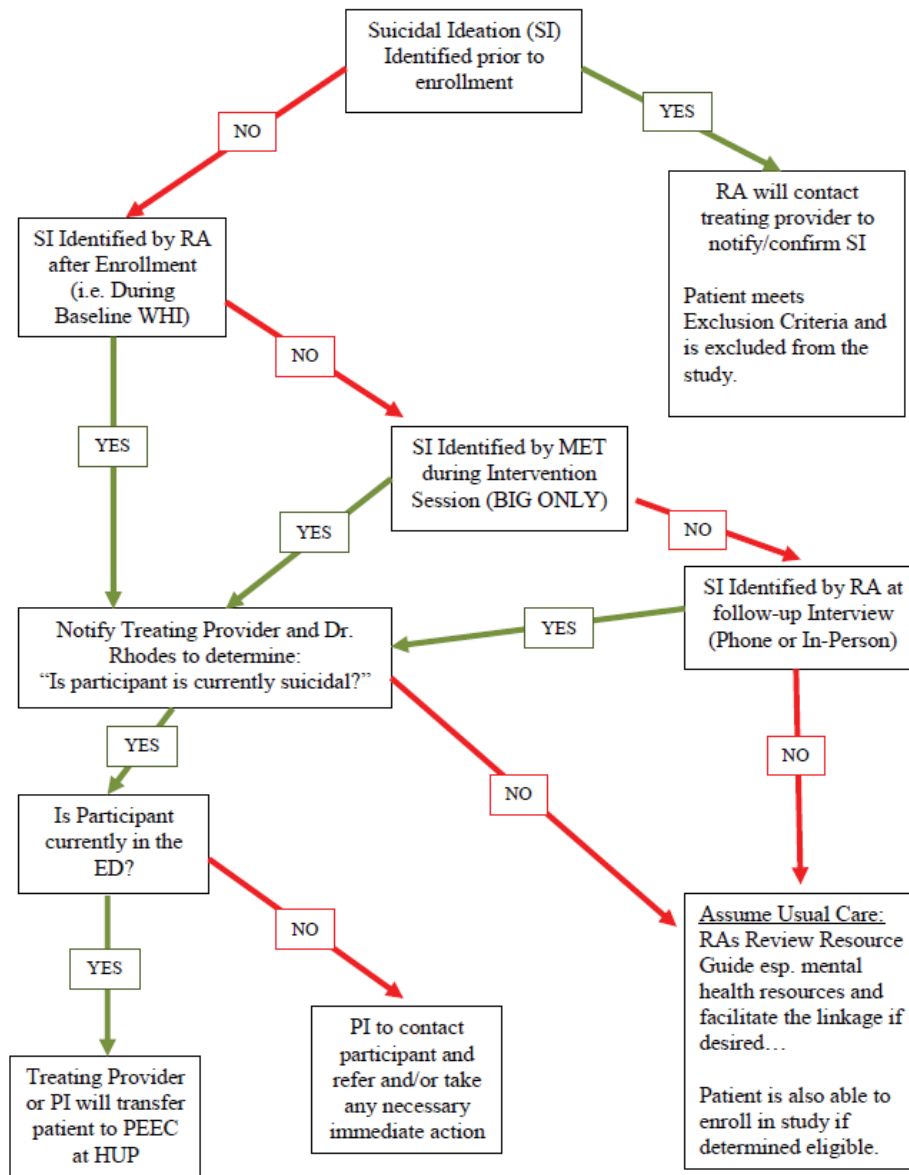
For ACG and BIG participants, the Baseline Women's Health Interview inquires if they were ever suicidal. For NCCG participants, the Follow-up Women's Health Interview inquires if they were ever suicidal. If they respond positively to this question, we will then ask whether they are currently experiencing suicidal ideation. If it is current, make a note and complete the survey. It is also possible that the patient will indicate suicidality without interview prompting. In any instance that a participant indicates they are experiencing current suicidal ideation, Dr Karin Rhodes should always be contacted as soon as possible (if she is unable to be reached please contact the Project Manager). Dr. Rhodes will aim to speak with the patient directly. Staff should also notify the attending physician of potential suicidality. **If at baseline, staff should aim to keep the patient at the hospital for further assessment.** If at follow-up, staff should aim to keep the patient on the phone for further assessment, or find an exact time for Dr. Rhodes to follow-up with the patient --- simply expressing that Dr. Rhodes likes to speak with patients after the follow-up interview to "check in".

If current suicidal ideation is identified:

1. As the reason for visiting the ED (psychosis or suicidal or homicidal ideation) and this is confirmed by the treating physician(s) prior to enrollment, they meet exclusion criteria and will not be enrolled.

2. During a baseline or follow up interview or by the MET therapist during the intervention (BIG participants only), research assistants are to share this information with the treating physician and ideally notify Dr Rhodes, so she can speak to the patient or treating physician by phone at the time of the visit.
3. If current suicidality is confirmed by Dr Rhodes (or the treating physician) and the participant is...
 - a. In the Emergency Department, Dr Rhodes or the treating physician will evaluate and if needed make arrangements for the patient to be transferred to psychiatric emergency evaluation center (PEEC) at HUP.
 - b. If not in the Emergency Department, Dr Rhodes will refer the participant to a treating psychiatrist and if needed Dr Rhodes can call the behavioral mental health crisis team or the police if in her judgment the patient might be an immediate danger to themselves or others and requires an escort for further evaluation and treatment.
4. If the patient reports suicidal ideation but is not considered to be actively suicidal following assessment by the treating physician and/or Dr Rhodes, then:
 - a. Research staff will review the resource guide provided to all enrolled participants and will specifically point out mental health resources and facilitate the linkage to such resources if desired by the patient.
5. Using our intent-to-treat approach, once enrolled, unless a patient withdraws from the study, we and they will continue with study activities as long as it does not appear to exacerbate risk.

Suicidal Ideation Decision Tree for Research Staff Use



Section 8 Summary of Modifications to Study Protocol

The protocol presented in sections 1 through 7 is reflective of our initial study protocol and various refinements over the first 10 months of enrollment. Below is a summary of the modifications to our study protocol. All modifications were submitted to the University of Pennsylvania Institutional Review Board and approved and implemented within one to two months. Modification summaries ordered by date of submission to the IRB.

January 21, 2011

Our project will be temporarily providing cash incentives to participants as opposed to the electronic gift-card based incentive. This will directly impact the incentive schedule, as the payment will not be instantaneous but will be given at the time of follow-up:

1. Participants will receive cash who enroll in the study for their participation in research tasks while in the HUP ED. Participants will then complete the weekly tasks across 12 weeks without instantaneous payment and when they return to the ED for their 3 month follow-up visit, we will provide them with a debit card that has their entire earned amount on it.
2. The only difference is the instantaneous aspect of payment – participants will have to wait until they return to the ED to receive their 12 weeks' worth of payments. The actual amount that participants receive will not be affected by this change in protocol.
3. We absolutely do not want to change our reimbursement protocol and fully intend on using the electronic debit gift cards as laid out in our original IRB submission. PNC has provided us with a finalized contract that is currently being reviewed by appropriate parties at Penn; as a result, this is a temporary incentive alternative.

February 16, 2011

1. We have made edits to all three versions of the Women's Health Interviews (See attached revised women's health interviews – a track changes version and clean copy of each). The key revisions include:
 - a. Subject Name has been removed from this data collection form.
 - b. For questions regarding the participants "partner" we have clarified which partner we are referring to, their current partner or their "index" partner. Interviewers are instructed to determine the "Index" partner's first name or a code name and use it as a reference point when asking questions that should specifically refer to the partner from the violent relationship, who qualified them for the study. This information is captured on the first page of each interview. On the follow-up interview (2 versions) we have expanded the question about current relationship or dating status to ensure we collect the participants' current relationships and identify whether they are still involved with the "Index" partner.
 - c. We have shortened the interviewer's script for the Timeline Follow-Back portion of the interview in the Baseline WHI. For the three follow-up interviews that can be completed over the phone, we have also decided to collect comparable TLFB data using estimates for a shorter timeframe (the last 30 days). This method is suggested by Sobell and colleagues (1996) when collecting TLFB by phone, as it is shorter and has less recall bias. This method has been validated and found to be comparable to the traditional TLFB calendar method that will be used in our baseline interview.
 - d. We have added a supplemental "Relationships Satisfaction" question to the follow up interviews to ensure we capture whether the woman is answering this question for a new or "Index" partner.
 - e. For participants who respond yes to the question "Have you ever threatened or tried to commit suicide?", we have added a conditional question that inquires if suicidal ideation is current, in order to effectively address this potential exclusion criteria, and allow for mandated reporting/medical intervention.
 - f. A supplemental measure of "readiness to change" has been added to better capture a stage of change at baseline (key moderating factor) and any changes in stage of change over time.
2. We have made edits to our Study Face Sheet – Personal Information. Primarily we've removed unnecessary medical record information. (See attached revised Study Face Sheet – a track changes version and clean copy).
3. We have improved our Safe Contact Form by capturing additional details about participants willingness to be contacted during the course of the study and best times/days to reach the participant (See attached revised Study Face Sheet – a track changes version and clean copy).
4. Our study database and filing systems have been fully developed and we have elected to clarify our data and subject confidentiality procedures. These changes are not different in intent or function, but rather

update the way we have operationalized our goals for protecting data confidentiality that we initially set forth at project onset.

5. We obtained our Federal Certificate of Confidentiality (CoC) on August 4th, 2010 , and have updated our consent form to reflect this. No other changes were made to the consent documents. (Please see attached revised informed consent document, with changes indicated in Track Changes and in clean copy). We have also attached copy of our CoC.
6. For the BIG participants receiving the MET intervention, we have decided to (optionally) audio-record the MET Booster session, which occurs over the phone 7-10 days following the intervention. As a result, we have updated our audio-taping consent document to reflect this change. (Please see attached revised audio-taping consent document, with changes indicated in Track Changes and in clean copy.)
7. We have modified our protocol to allow for ED provider referrals of IPV or alcohol abusing patients. If during data collection times, they will simply notify a study RA. If ED providers identify a woman who might be eligible and interested in the study outside of data collection times, with her verbal permission, they will collect safe contact information and leave the information in a locked box, which will be checked daily during data collection times. The patient will then be contacted using her safe contact information and screened for eligibility over the phone. If eligible, the study will be explained and she will be offered an opportunity to return to the ED for consenting, enrollment and randomization procedures.

April 1, 2011

1. Please find a track changes document highlighting specific edits to the Women's Health Interview and clean updated versions of the 3 Women's Health Interviews.
 - a) TimeLine Follow-Back: Based on the advice of co-investigators, we have decided to collect traditional TLFB data for the past 30 days at time of follow-up, rather than use the 4 questions summarizing number of drinks within 3 ranges (Note: this retracts the edit submitted with our 2-16-2011 Modification). We have shortened the timeframe for the Timeline Follow-Back portion of the interview in the three follow-ups so that it is more easily conducted over the phone. This method will still decrease respondent burden and result in less recall bias, but also allows us to make effective comparisons among our alcohol measures at various points throughout the study. This change does not affect data collection as no follow-ups have yet been completed.
 - b) Supplemental Drug Use Questions: Based on the advice of Linda Degutis, a member of a DSMB and director of the National Center for Injury Prevention and Control, we have decided to include a specific question regarding the use/misuse of prescription drugs. Prescription drugs were previously embedded in the illicit (street) drugs category.
 - c) Readiness to Change Measure: We have decided to revise our Readiness to Change Image and questions text. This question was added in our February 2011 modification.
 - d) Treatment Services Review: Based on the advice of our Co-Investigators, we have decided to include a few additional questions on the Women's Health Interviews regarding the participant's receipt of treatment during study participation. A total of 2 questions will be added to the Follow-up WHIs and 1 question will be added to the baseline "Engagement in Treatment" Section.
 - e) Removal of Motivation to Change Rulers at Follow-Up: Since the Readiness to Change Measure has been added to the follow-up interviews, we have decided that the Importance and Confidence rulers (4 questions), should be removed at the time of follow-up. These measures are moderators and therefore only need to be measured at baseline. Their removal will also decrease respondent burden.

2. Currently as part of our protocol, we are accepting patient referrals from providers outside of data collection periods. As part of routine care in the HUP ED, each patient completes a Social Health Survey where he/she can report various psychosocial risks, including intimate partner violence and risky drinking. Providers are aware of our ongoing study and if a patient presents with either of our targeted risks, they are encouraged to ask the patient whether or not they would be interested in participating in a research study that focuses on women's health. If the patient responds positively, providers can complete a "Safe Contact" form to collect safe contact information from the patient (Submitted). This form is then stapled to the Social Health Survey and deposited into a locked bin. Research staff empties these bins each morning and follow up with the patient.

May 1, 2011

1. Please find a track changes document highlighting specific edits to the Women's Health Interview and clean updated versions of the 3 Women's Health Interviews.
 - a. CES-D Depression Scale: We have decided to change our CES-D Depression Scale to the shortened 10 – item version. Upon noticing that one of the 20 items was left off the initial interview, we determined that the best resolution was to use the shorted 10-item version of this scale which has been validated by Andreson, Malmgren, Carter, & Patrick, (American Journal of Preventative Medicine, 1994). This will also reduce respondent burden, but also allow us to account for depressive symptoms using a validated tool in our outcomes analysis. This change will be made to all 3 versions of the WHI and will not impact data collected thus far.
 - b. Sexual Abuse History: We have decided to alter the first sexual abuse question response scale from a 5 item likert to a binary Yes/No. Feedback from staff and a review by study co-Investigators determined that this information would be better collected using a Yes/No response; also, during analysis participant sexual abuse history will be analyzed as a binary moderator. This change will be made to the Baseline & NCCG 3-month follow-up; data collected thus far will not be lost due to this change.

July 7, 2011

The electronic gift-card based incentive structure has been setup and finalized. We will soon begin providing all newly enrolled participants with gift card incentives, and no longer be deviating from the compensation procedure by providing cash incentives to study participants. As a result we have updated our consent form to indicate that participants will be compensated for completed study activities using a wirelessly reloadable gift card. They will receive payment within 1 to 2 business days for completed phone surveys and follow-up interviews, without having to return to the Emergency Department. In addition, all language reflecting deviation from our compensation procedure has been removed from the IRB study protocol.

Participants enrolled prior to the official launch of the gift cards will continue to receive cash incentives. For those participants who have not yet passed their 3-month follow-up, they will be provided payment for all unpaid completed study activities on a gift card at their 3-month appointments. Those that are past their 3-month time-point will receive payment for remaining 6 & 12 month follow-ups in cash. Participants will not be re-consented as this potential change in procedures was explained to them in the consent they signed at enrollment.

September 8, 2011

This modification is being submitted to expand our data collection to the Emergency Department at Penn Presbyterian Medical Center. Currently, we are enrolling eligible patients from the Emergency Department (ED) at HUP. While we are meeting our anticipated enrollment, we would like to increase the number of patients screened for intimate partner violence (IPV) and risky drinking and potentially increase our enrollment numbers to more quickly reach our enrollment goals. In order to do so, we plan on expanding to the ED at Penn Presbyterian. This expansion would involve an identical replication of the data collection process currently being executed at HUP, including all IRB-approved protocols regarding recruitment, study procedures, data storage, and consent procedures.

October 21, 2011

In response to our first Data Safety Monitoring Board meeting, this modification is being submitted to adjust our incentive structure, to clarify our protocol around disclosure of suicidal ideation and/or suicidality, and to add a short satisfaction questionnaire to be asked of all participants at 3-month follow-up.

Increasing participant payment: Currently, we pay participants \$10 at the time of enrollment. If the participant is in a group that requires an IVRS phone call at baseline, they are paid an additional \$10. We have decided to increase the base pay at enrollment to \$30, regardless of group membership. If the participant is in a group that requires an IVRS phone call at baseline, their \$30 enrollment payment will be inclusive of completing their first call and they will no longer receive separate payment for this call - All participants will leave with a gift card that has a \$30 balance. ACG/BIG participants who complete the final IVRS will continue to be paid the bonus of 5 dollars for every completed call - including their first call. The consent forms have been edited for this modification.

Clarify Suicidal Ideation Protocol: The DSMB asked for clarification around our Suicidal Ideation Protocol. Upon review of our IRB protocol, we noticed the misuse of the term "exclusionary criteria." If a patient is enrolled in the study and they **then** report Suicidal Ideation (typically on the Danger Assessment, which is only collected from enrolled participants), this person will not be excluded from the study. Only if Suicidal Ideation is disclosed before study enrollment (or documented in the patient's chart) will it be viewed as an exclusionary criterion. Regardless of whether the individual is a study participant or not, if patients disclose to research staff that they are having suicidal thoughts, the staff member will immediately notify the treating physician and the individual will receive further assessment. In sum, no changes have been made to our protocol (as outlined in *Protection Against Suicidal/Homicidal Risk*), simply clarifications.

Assess satisfaction with innovative technologies being used: Our study implements two innovative technologies: PNC gift cards for wireless incentive payments, and Interactive Voice Response (IVR) Surveys – or Phone surveys. The DSMB is concerned with participant acceptability of these technologies for both payment and data collection – especially in considering our phone survey retention rates. We decided to add a short 6 question satisfaction survey to be asked of all study participants at 3-month follow-up in regards to their satisfaction, preference, and problems encountered with the Gift Card and IVRS phone calls.

For IRB documentation of our DSMB activities, we have also attached a copy of our July 2011 DSMB report to this modification, as well as the DSMB letter of requested actions and our letter of response.

December 12, 2011

The approval of our previous modification (Submitted 10-21 and approved 11-22) included an increase to our enrollment incentive payment and thus changed our written consent form. At this time we are unable to implement this increase, as we are waiting on a potential administrative supplement in the new year.

The change in incentive payment was the only edits made to the consent form, so we would like to revert back to the written consent form approved on 7-13-2011 (valid through 3-20-2011). This modification is being submitted with three attachments of the written consent form. The first is the track changes version submitted on 10-21-2011. The second is a clean version of the approved consent form from the 7-7-2011 Modification. We would like to reject all track changes in the 10-21-2011 version and return to the previously approved consent form (version 7-7-2011). The attached pdf is the IRB stamped version of the consent form that we would like to use. In addition, edits made to the Subject Compensation Section of the Protocol were also reverted back to a \$10 enrollment payment instead of \$30. Should an administrative supplement be obtained, we will submit another modification to increase our incentives and update our consent form.

May 16, 2012

The following modification is being submitted to increase our participant incentive, update our study protocol regarding contact with enrolled participants and to make updates to our consent form. We are also reporting minor protocol deviations and corrective action taken in response to our regulatory OHR Audit conducted in January 2012. The following summarizes the modifications:

Increasing participant payment: Currently, we pay participants \$10 at the time of enrollment. If the participant is in a group that requires an IVRS phone call at baseline, they are paid an additional \$10. We have decided to

increase the base pay at enrollment to \$30, regardless of group membership. If the participant is in a group that requires an IVRS phone call at baseline, their \$30 enrollment payment will be inclusive of completing their first call and they will no longer receive separate payment for this call - All participants will leave with a gift card that has a \$30 balance. ACG/BIG participants who complete the final IVRS will continue to be paid the bonus of 5 dollars for every completed call - including their first call. This will be implemented for only newly enrolled patients and thus current participants will not be re-consented and will not receive the higher enrollment payment. We also updated the word bonus and replaced it with additional payment based on the IRBs recommendation.

Edits to Signature Section of Consent Form: We have decided to remove the following language from signature portion of the main study consent form: If I am selected for the social work health promotion session, I am willing to have the session audio-taped for teaching purposes. Yes/No; Signature of Subject. If the participant is not randomized to group 3 Intervention group who receives MET then they will not be audio-taped. Permission to audio-tape is obtained from group 3 participants once they are randomized, using a separate audio-recording consent. This Yes/No option has been determine obsolete since a separate audio-recording consent form is collected and its removal is part of the corrective action plan to address the ICF non-compliance of not completing all portions of the main study ICF.

Contact with enrolled study participants: We have edited our IRB Protocol and informed consent form to a process for research coordinators to check in with enrolled participants who return to the Emergency Department throughout their enrollment in the study. Many of our participants return to the ED which provides us with the opportunity to remind them about the study, complete study activities, and/or update contact information. The consent includes language that indicates: If you return to the ED as a patient during your enrollment period, a member of our research team may check in with you about the study regarding completion of study activities and to update your contact information.

SAE Contact Protocol: We have updated our protocol to state that we will notify the DSMB chair, rather than all 4 DSMB members, within 24 hours in the instance of a possible serious adverse event. It will be at the DSMBs discretion if DSMB members are consulted or a meeting is convened.

June 18, 2012

The following modification is being submitted to update our consent documents with contact information and also to include a statement about contacting unable to reach participants through updated contact information in their medical record. We are also seeking approval for the use of a generic website to establish another way for participants to maintain contact with the study.

1. We added a statement to our Informed Consent form to indicate additional ways in which the research staff may use information from their medical records at Penn. After a year and half of enrollment we have found that a large number of participants are being lost to follow-up as a result of disconnected and re-assigned phone numbers. We have also found high rates of ED recidivism (~34%) among our participants. In the event that we are unable to reach a participant (ie. Phone is disconnected and has been re-assigned, and their secondary contacts provide no assistance), we will review their medical record to determine if they provided updated contact information. If the phone numbers have been updated since their enrollment, we will contact the participant to determine if they are still interested in participating in the study. Staff will be provided with a script and specific protocol to ensure the safety of our study participants. (Attached to this Modification Submission)
2. We would like to create a generic website using our study's acronym (S.H.I.P – Social Health Improvement Project) and study contact information. We believe that making this generic information available through a free website will assist participants in making contact with the study team by either searching the internet for the SHIP – which is the how we refer to the study they are enrolling in. In addition, we have found that many of our participants lose the generic business card with the IVRS phone survey number on it, and would like to include a visual image of this card for their reference on the site. We have attached screenshots of the proposed site. Risk to participants will not be increased as they are provided with this information when they enroll in the study; making it available online just provides it in information in a different format.

July 26, 2012

The following modification is being submitted to adjust our incentive structure. We received an administrative supplement, which allows us to institute and graduated incentive structure at the 6 & 12 month data collection points. Currently, we pay participants \$20 for 6 & 12-month follow-ups. In order to engage participants to complete these two longitudinal measures, we have increased the 6-month WHI to \$30 and the 12-month WHI to \$50. The consent forms and IRB protocol have been edited for this modification.

By way of update to our previously reported deviations (5-2012), we have obtained 2 of the 3 participants who did not sign the audio-consent but were recorded at their follow-up appointments. The one remaining subject did not indicate "NO" on the study consent and as a result, we will keep this de-identified tape for analysis. As previously stated, our rationale is that the recording was designated as optional on the original consent form and participation in the audiotaping process was not rejected by the participant.

September 25, 2012

The following modification is being submitted to update our screening procedures to include the routine social health screening that is being completed by some patients on a computer. Dr. Rhodes is the PI on an IRB approved study (Protocol #812073, Evaluation of self-administered computerized survey in the ED) to develop and implement a computer assessment called Promote Health in the HUP and PPMC waiting rooms. It is the EDs plan to move away from the current paper-based Social Health Survey that is part of routine clinical care to a computer-based version where the patient entered data will be available for provider review and copying and pasting into the patients' medical record as patient-entered data. The Promote Health assessment includes a review of systems (ROS) and Family History (FH), as well as most of the questions that are mandatory to be asked in triage and those that are on the paper Social Health Survey. Since the Promote Health Assessment is in the early phases of implementation and testing, many patients will continue to be screened with the paper Social Health Survey until the computer version of the program is fully implemented into routine care. However, because a portion of the patients engaged during data collection times will be completing the computer assessment, we don't want to also ask them to complete the paper version of the SHS. So, for patients that have completed the Promote Health Assessment, we will have staff review the same screening information on the computer version, which is stored electronically in Emtrac. We have auto-coded the screening questions so that based on patient responses the Social Health Bin auto-populates with a positive (+), negative (-), or blank (if not answered) for RA ease of identifying a woman who may be eligible for further assessment for study eligibility. This change in procedure has been reflected in the IRB protocol. Please note that this does not impact the responses which screen in participants and all participants will continue be assessed for study eligibility using the CTS2S and AUDIT.

We are also submitting revised consent forms updating the contact information for Dr. Rhodes and the Emergency Contact. We will not re-consent previously enrolled participants.

Appendices Index

Social Health Survey & Resources

Screener's Tracking Form

Eligibility Assessment Form – CTS2S & AUDIT

Safe Contact Plan

Participant Demographics Sheet

Baseline Women's Health Interview

Follow-up Women's Health Interview (ACG & BIG)

NCCG Follow-up Women's Health Interview

Timeline Follow Back Calendar Form

Script for Interactive Voice Response (IVRS)

MET Booster Form

Date: _____

ED Trauma Unit

**University of Pennsylvania Emergency Department and Trauma Unit
SOCIAL HEALTH SURVEY**

To more fully address our patients' overall health, we are asking questions about home life, emotional health, and lifestyle. Some of the questions are about personal issues. You can skip any question that you do not want to answer, or not complete the survey at all. Your decision to complete this survey will not influence your ability to receive care.

PLEASE TAKE THIS SURVEY IN PRIVATE AND GIVE IT TO THE DOCTOR OR NURSE TAKING CARE OF YOU TODAY ONLY IF YOU WANT TO.

Please feel free to tear off and keep the attached list of resource numbers.

CIRCLE/CHECK YOUR ANSWER OR FILL IN THE BLANK. SKIP ANY QUESTIONS THAT YOU DO NOT WISH TO ANSWER OR THAT DO NOT APPLY.

1. AGE _____							
2. SEX <input type="checkbox"/> _F Female <input type="checkbox"/> _M Male If female, is there a chance you may be pregnant? YES NO Not Sure							
3. How would you rate your overall health?		Poor	Fair	Good	Very Good	Excellent	
4. How many people live in your home? <input type="text"/>							
5. Do you have children? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many? _____ How many live at home? _____							
6. Have you smoked ANY cigarettes in the last 12 months?				YES	NO	Not Sure	
7. How many times in the past year have you had 4 or more drinks in a day? <input type="text"/>							
8. On average, how many days a week do you have an alcoholic drink? 0 1 2 3 4 5 6 7							
9. On a typical drinking day, how many drinks do you have? 1 2 3 4 5 6 7 8 9 10 More than 10 (how many? _____) <input type="checkbox"/> N/A – I don't drink							
10. Does anyone you live with have a drinking problem?				YES	NO	N/A	
11. Have you used ANY street drugs in the last 4 weeks?				YES	NO	Not sure	
12. Do you have a job outside the home?				YES	NO	Not sure	
13. Do you have enough money to meet your needs?				YES	NO	Not sure	
If NO:	Do you sometimes eat less than you would like because of money concerns?				YES	NO	Not sure
	Have you ever not seen a doctor when you needed to because of money concerns?				YES	NO	Not sure
	Have you ever not taken medications you needed because of money concerns?				YES	NO	Not sure
Emotional Health							
14. Do you have someone you can talk to about any problem?				YES	NO	Not sure	
15. Do you have someone you could stay with if needed?				YES	NO	Not sure	
16. Do you have someone you could borrow money from if needed?				YES	NO	Not sure	
17. Has anyone close to you left you or died recently?				YES	NO	Not sure	
18. In the last 12 months have you felt sad or depressed for more than 2 weeks in a row?				YES	NO	Not sure	
If YES:	In the last 2 WEEKS, have you felt sad or depressed most of the time?				YES	NO	Not sure
19. How much STRESS are you under?		None ₀	Just a little ₁	Normal amount ₂	Too much ₃	Extreme ₄	
20. Are you able to adapt when changes occur?		Not at all ₀	Rarely ₁	Sometimes ₂	Often ₃	Nearly Always ₄	
21. Do you tend to bounce back after illness, injury or other hardships?		Not at all ₀	Just a little ₁	Sometimes ₂	Often ₃	Nearly Always ₄	

Over please →

Stress and Conflict in Relationships			
IN THE LAST YEAR....			
22. Has ANYONE in your life hit or physically hurt you?	YES	NO	Not sure
If YES: Did this happen with a current or former partner (husband/wife, lover, boy/girlfriend, ex-partner, or someone you have a child with)?	YES	NO	Not sure
23. Does someone you live with have a problem controlling his/her anger?	YES	NO	Not sure
24. Do YOU have a problem controlling your anger?	YES	NO	Not sure
25. Have YOU hit or physically hurt a partner?	YES	NO	Not sure
26. Do you currently feel threatened or afraid of anyone?	YES	NO	Not sure
If YES: Is this person a: <input type="checkbox"/> _{CP} Current partner? <input type="checkbox"/> _{FP} Former partner? <input type="checkbox"/> _{FR} Friend? <input type="checkbox"/> _{FM} Family member? <input type="checkbox"/> _S Someone else?			
27. Have the police been called because of a fight between you and a partner?	YES	NO	Not sure
28. Have you had a new sexual partner in the last 12 months?	YES	NO	Not sure
29. Do you ALWAYS use a condom during sex?	YES	NO	N/A
30. Have you EVER been made to have sex when you didn't want to?	YES	NO	Not sure
If YES: When did this happen: <input type="checkbox"/> _C as a child? <input type="checkbox"/> _A as an adult? With: <input type="checkbox"/> _{CP} a current partner? <input type="checkbox"/> _O other?			
Injury Risk Factors			
31. Does anyone in your home have access to a gun?	YES	NO	Not sure
If YES: Is the gun kept unloaded AND in a locked place?	YES	NO	Not sure
32. Do you have a working smoke detector in your home?	YES	NO	Not sure
33. When you are in a car, do you ALWAYS use your seatbelt?	YES	NO	Not sure
34. When you ride a bike, do you ALWAYS wear a helmet?	YES	NO	N/A

35. Is the reason for your visit today related to:

- _I An injury? If yes, what caused your injury? (motor vehicle crash? fall? other cause?) Specify _____
- _A A new illness or medical problem? Specify _____
- _C A long-standing medical problem? Specify _____
- _S Stress or worry? Specify _____
- _O Other? Specify _____

36. What is your current relationship status? (check all that apply)

- _S Single _D Dating _M Married/Partnered _L Living with a current/former partner
- _P Separated from a partner (divorced, widowed, broken up) in past year

37. What is your race/ethnicity?

- _W White _B Black _H Hispanic _A Asian _M Mixed Race _O Other

38. How far did you go with your education?

- _L Less than high school _H High school/equivalent _S Some college _C College graduate/higher

39. Do you have concerns about any of the following?.

- | | | |
|---|---|--|
| <input type="checkbox"/> _Y <input type="checkbox"/> _N Stopping smoking | <input type="checkbox"/> _Y <input type="checkbox"/> _N Sexual health | <input type="checkbox"/> _Y <input type="checkbox"/> _N Help w/older family member |
| <input type="checkbox"/> _Y <input type="checkbox"/> _N Use of street drugs | <input type="checkbox"/> _Y <input type="checkbox"/> _N Anger management | <input type="checkbox"/> _Y <input type="checkbox"/> _N Relationship problems |
| <input type="checkbox"/> _Y <input type="checkbox"/> _N Drinking problem | <input type="checkbox"/> _Y <input type="checkbox"/> _N Housing | <input type="checkbox"/> _Y <input type="checkbox"/> _N Can't afford medication |
| <input type="checkbox"/> _Y <input type="checkbox"/> _N Not enough food | <input type="checkbox"/> _Y <input type="checkbox"/> _N Insurance | <input type="checkbox"/> _Y <input type="checkbox"/> _N Health/Dental care |
| <input type="checkbox"/> _Y <input type="checkbox"/> _N Nerves or anxiety | <input type="checkbox"/> _Y <input type="checkbox"/> _N Employment | <input type="checkbox"/> _Y <input type="checkbox"/> _N Other: _____ |
| <input type="checkbox"/> _Y <input type="checkbox"/> _N Depression | <input type="checkbox"/> _Y <input type="checkbox"/> _N Child health/safety | |
| <input type="checkbox"/> _Y <input type="checkbox"/> _N Free HIV testing | <input type="checkbox"/> _Y <input type="checkbox"/> _N Family violence | |

40. Which of the above is your top concern? _____

THANK YOU FOR COMPLETING THIS SURVEY!
Please tear off and keep the attached list of resource numbers.

Social Service Resource Guide: Philadelphia Area

Child Health/Child Care

Maternal, Child & Family Health Line

www.choice-phila.org

English: 215-985-3301

Spanish: 215-985-3350

Information, counseling, referrals, and advocacy regarding pregnancy, prenatal care, and children's medical care and free/low-cost health insurance.

Child Care Works Hotline

877-4PA-KIDS (English & Spanish)

Help to low-income families in paying child care fees.

Child Care Information Services of Philadelphia

888-461-KIDS

Assistance finding, selecting, & paying for quality childcare

Smoke Detectors Hotline

215-686-1176

Free smoke detectors

Employment

Philadelphia Unemployment Project www.philaup.org

215-557-0822

Assistance with job searches, mortgage and rent payment and unemployment claims, welfare, and health care coverage

Philadelphia Workforce Development Corp. www.pwdc.org

215-557-2625

Assistance with job training, resumes, and job placement

Philadelphia Employment Guide Website

<http://philadelphia.employmentguide.com/>

Great resource for job searches, job fairs, and trainings

Housing

"The Housing Locator" www.HUD.gov/rentinglocal

215-656-0500

Listing of homes & HUD-subsidized rental facilities; housing counseling

Office of Supportive Housing

215-686-7150 (Women, Families, and Couples)

215-236-0909 (Men)

Shelter placement

Resources for Human Development/ EndowAHome

215-951-0330

Services for single mothers over age 21 with children under 18 and a Section 8 certificate/voucher.

Covenant House of PA

1-888-829-1249

Shelter and services for homeless youth 18-21

Food and Nutrition

Food Stamp (SNAP) Hotline

215-430-0556

Philabundance Food Help Line

215-339-0900

Referrals to food resources; emergency food boxes

WIC: Philadelphia County Office

215-978-6100

Supplemental food for pregnant/breastfeeding women and children under 5 years

Counseling/Behavioral Health

Center for Family and Relationships

215-537-5367

Individual and group counseling for couples.

Suicide & Crisis Intervention Hotline

215-686-4420 (24 Hours; English & Spanish)

Counseling and referrals for people in crisis

Mental Health Association of Southeastern PA

215-751-1800

Employment assistance, drop-in centers, residential shelters, and mental health referrals regardless of insurance status

Community Behavioral Health www.bhids.org

88-545-2600 (24 Hours; English & Spanish)

Counseling and substance abuse treatment for Medical Assistance (Medicaid) recipients

Alcohol & Drug Abuse Resource Center

800-390-4056

Behavioral Health Special Initiative

215-546-6435

Treatment services for uninsured individuals

Narcotics Anonymous www.na.org

215-NA-WORKS (English & Spanish)

Alcoholics Anonymous www.aa.org

215-923-7900

Smoking Cessation

1-800-QUIT-NOW (24 Hours; English & Spanish)

Children's Crisis Treatment Center

215-496-0707 (24 Hours; English & Spanish)

Mental health services for children and families to address the effects of abuse and trauma

Mental Health Delegate

215-685-6440 (24 Hour mobile emergency teams)

Older Family Member Help

CARIE Line

215-545-5728

Information and referrals to community resources with special assistance to victims of crime and elder abuse

Philadelphia Corporation for Aging

215-765-9040 (English and Spanish)

Services ages 60+. In-home support, advocacy, employment & legal assistance, transportation, caregiver support, & PACE applications.

Sexual Health/Sexual Violence

AIDS Activity Coordinating Office (AACO)

215-985-2437 (English/Spanish)

Coordinates HIV/AIDS planning and policy activities throughout Philadelphia

CHOICE Hotline

215-985-3300 (English)

215-985-3350 (Spanish)

Education and referrals for birth control, emergency contraception, OB/GYN care, pregnancy and prenatal care, abortion, testing for HIV/AIDS and STDs.

Community AIDS Hotline

215-985-AIDS (English & Spanish)

Esfuerzo (HIV/AIDS) Program

215-763-8870, ext. 7101

AIDS Services in the Asian Community

215-563-2424, ext. 12

Anonymous Rapid HIV Testing

215-685-6571

Planned Parenthood of SE Philadelphia

www.plannedparenthood.org/ppsp

215-351-5560 (English & Spanish)

Women Organized Against Rape www.woar.org

215-985-3333 (24-hour hotline)

Sexual abuse counseling, support groups, court advocacy, and hospital accompaniment.

Legal Assistance

Community Legal Services of Philadelphia www.clsphila.org

215-981-3700

Disability Rights Network of PA

1-800-692-7443

Nationalities Service Center

215-893-8400

Social, legal, and translation services for immigrants and refugees

Temple Legal Aid Office

215-204-1800

Women Against Abuse Legal Center

215-686-7082

Violence and Abuse

Philadelphia Domestic Violence Hotline & Women

Against Abuse Shelter www.womenagainstabuse.org

866-723-3014 (24 Hours; English & Spanish)

Shelter, counseling, and legal information for victims of domestic violence

Congreso De Latinos Unidos www.congreso.net

215-763-8870 (English & Spanish)

Education, support and counseling services for victims of domestic violence and their children

Lutheran Settlement Domestic Violence Program

215-426-8610 ext.236 (English & Spanish)

Free individual and group counseling services for victims or former victims of domestic violence

Menergy www.menergy.org

215-242-2235 (English)

267-625-6135 (Spanish)

Counseling for men and women who have been abusive to their intimate partners

Women in Transition

215-564-5301

Free help to women in an abusive relationship with a male or female partner; help for women confronting addictions

To report child abuse:

Department of Human Services (DHS)

215-683-6100 (You do not need to give your name)

National Teen Dating Abuse Helpline

866-331-9474 (24 hours)

Healthcare Resources

HUP ED Social Work Staff

215-662-3905

Can arrange emergency healthcare insurance

Philadelphia Department of Public Health

Community Health Centers

215-685-6790

Low-cost or free medical and dental care

United Community Clinics (Monday evenings only)

484-238-0822 Free healthcare clinics run by medical, nursing, and social work students

Mary Howard Health Center

215-592-4500

Healthcare for homeless individuals

Mazzoni Center www.mazzonicenter.org

215-563-0652

Comprehensive healthcare for LGBTQ individuals

WalMart and Target offer \$4.00 generic prescription medications.

Screener's Tracking Form
WHS: Brief Intervention Related to Drinking and Relationship Conflict

Study Criteria

- **Female age 18-64**, (cognitively intact, not acutely sick (check back later in visit))
- **Risky drinking**: Consume >4 alcoholic drinks on any occasion or >7 drinks per week (questions #7-9 on the green Social Health Survey)
- **Partner Violence**: Any "YES" response to questions #22-27 or question #30 (**with current partner**) on the Social Health Survey

If woman meets either criterion → administer Eligibility Assessment (CTS2S and AUDIT surveys).

Patients are eligible if: Audit = 4 or higher **AND** CTS2S = 1 or higher

★ Date: ___/___/___ Shift: _____-_____

Screener Name: _____

Encounter #	Rm #	Pt Age	Chief Complaint (code)	Referred by ED Staff?	Time (Est. Apprch)	Approach (Y/N)	If no, why? (code)	Screen w/ SHS (Y/N)	If no, why? (code)	SHS (+ / -)		Assessed (Y/N)	If no, why? (code)	Eligibility Assess Scores		Eligible (Y/N)	Enrolled (Y/N/C)	If no, why? (code)	If yes, Assign Study ID
										ALC	IPV			CTS2S	Audit				
				<input type="checkbox"/>															
				<input type="checkbox"/>															
				<input type="checkbox"/>															
				<input type="checkbox"/>															
				<input type="checkbox"/>															
				<input type="checkbox"/>															
				<input type="checkbox"/>															
				<input type="checkbox"/>															
				<input type="checkbox"/>															
				<input type="checkbox"/>															

Chief complaint codes: (I)njury (M)edical (GU)GYN/Urinary (P)sych/Sub. Abuse/OD (O)ther

Not Approached/Screened/Assessed codes: (NA-F) Family/Others present. (NA-M) Receiving medical care. (NA-S) Sleeping. (NA-E) Severe Emotional/Psychological Distress
 (SH) Suicidal / Homicidal Ideation (CI) Cognitive Impairment / Psychosis (NA-D) Under the influence of med/drug/ alcohol
 (ND) Not English-speaking (J) Incarcerated/Arrested (O) Other (P) Physical Illness/Physically unable/Pain
 (A) Admitted (DC) Discharged / Has left the ED (D) Declined (NOT SCREENED & NOT ASSESSED ONLY)

Not Enrolled: (CI) Cognitive Impairment / Psychosis (MU) Medically (Physical/Emotional) Unable to participate (SH) Suicidal or Homicidal Ideation (J) Incarcerated/Arrested
 (PE) Previously enrolled in Study (NI) Not interested (UC) Unable to Contact (SC) Safety Concern (O) Other (Note Reason)

If Eligible, EN#: _____

If Enrolled, Study ID: _____

Date: ____/____/____

Women's Health Study Eligibility Assessment Form

CTS2S

No matter how well a couple gets along, there are times when they disagree, get annoyed with the other person, want different things from each other, or just have spats or fights because they are in a bad mood, are tired, or for some other reason. Couples also have many different ways of trying to settle their differences. This is a list of things that might happen when you have differences.

Have you had any contact with a current or former partner IN THE PAST THREE MONTHS?

Yes No (If NO, CTS2S Score = 0 → Continue to AUDIT)

If yes, how many times did these things happen IN THE PAST THREE MONTHS?

0 = This never happened

5 = 11-20 times in the past three months

1 = Once in the past three months

6 = More than 20 times in the past three months

2 = Twice in the past three months

P = DID NOT HAPPEN IN THE PAST THREE

3 = 3-5 times in the past three months

MONTHS, but it has happened before

4 = 6-10 times in the past three months

1. I insulted or swore or shouted or yelled at my partner.	0	1	2	3	4	5	6	P
2. My partner insulted or swore or shouted or yelled at me.	0	1	2	3	4	5	6	P
3. I had a sprain, bruise, or small cut, or felt pain the next day because of a fight with my partner.	0	1	2	3	4	5	6	P
4. My partner had a sprain, bruise, or small cut, or felt pain the next day because of a fight with me.	0	1	2	3	4	5	6	P
5. I pushed, shoved, or slapped my partner.	0	1	2	3	4	5	6	P
6. My partner pushed, shoved, or slapped me.	0	1	2	3	4	5	6	P
7. I punched, kicked, or beat-up my partner.	0	1	2	3	4	5	6	P
8. My partner punched, kicked, or beat-me-up.	0	1	2	3	4	5	6	P
9. I destroyed something belonging to my partner or threatened to hit my partner.	0	1	2	3	4	5	6	P
10. My partner destroyed something belonging to me or threatened to hit me.	0	1	2	3	4	5	6	P
11. I went to see a doctor or needed to see a doctor because of a fight with my partner.	0	1	2	3	4	5	6	P
12. My partner went to see a doctor or needed to see a doctor because of a fight with me.	0	1	2	3	4	5	6	P
13. I used force (like hitting, holding down, or using a weapon) to make my partner have sex.	0	1	2	3	4	5	6	P
14. My partner used force (like hitting, holding down, or using a weapon) to make me have sex.	0	1	2	3	4	5	6	P
15. I insisted on sex when my partner did not want to or insisted on sex without a condom (but did not use physical force).	0	1	2	3	4	5	6	P
16. My partner insisted on sex when I did not want to or insisted on sex without a condom (but did not use physical force).	0	1	2	3	4	5	6	P
Total Column Score	0							0

Grand Total = _____

CTS2S ≥1 indicates positive for current IPV

AUDIT

Questions	0	1	2	3	4
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 or more times a week
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
3. How often do you have four or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
8. How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
9. Have you or someone else been injured as a result of your drinking?	No		Yes, but not in the last year		Yes, during the last year
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year
Column Total	0				

GRAND TOTAL = _____
AUDIT \geq 4 is positive

University of Pennsylvania
Women's Health Study
INDIVIDUALIZED SAFE CONTACT PLAN

Participant Name: _____
Last First Middle I.

Group Assignment: NCCG ACG BIG

Date of Contact Plan ____/____/____

Check Here if Participant does NOT want to be contacted during follow-up.

"Your safety is our primary concern. We need to make a safe plan for contact. We do not want to call when your partner is around or can listen in on the conversation."

Please provide information about the best ways and times to reach you."

1. What time do you prefer us to call you?

Day (please circle): M T W Th F Sa Su Time (please circle): Mornings Afternoon Evening

2. Are there any times when we should NOT call you?

Day (please circle): M T W Th F Sa Su

Time (please circle): Mornings Afternoon Evening

3. Is it ok for us to send you generic health tip reminders to your home address? Yes No

4. Is it ok for us to send you text messages with study reminders using generic messages? Yes No

Sample: "Penn Medicine cares about your health. This is a friendly reminder. Call to schedule your next visit: 215-573-3055. Do not reply"

Is it safe to leave a message from 'the University of Pennsylvania's SHIP project'?

How should we introduce ourselves if someone else answers the phone (e.g. UPenn ER; SHIP project)?

"If you are speaking with us and it suddenly becomes unsafe, you can just hang up, or say anything you want. We will understand that you cannot talk anymore at that time. You do not have to explain. If this happens, would it be okay for us to call you again later? How should we reach you? Do you want to use particular code words to indicate that it is not safe for you to continue the call at that time? Please provide any information that might be helpful."

"If you want us to call the police, what code words would you like to use? If we call the police, where would you like us to send them?"

"If at any point, you would like to contact us or have any questions or concerns, please call the confidential study hotline at: 215-573-3055" [give Women's Health Study card]

1. What is your phone number?

Home (____) _____ - _____ Okay to leave a message? Yes No
 Work (____) _____ - _____ Okay to leave a message? Yes No
 Cell (____) _____ - _____ Okay to leave a message? Yes No Okay to text? Yes No

2. What is your current address? Okay to send newsletter? Yes No

“In the event that we are unable to get in touch with you we may, with your permission, contact people you trust who may be able to help us reach you. We will not share any information with anyone we contact about the nature of the study or information you share with use. Please provide contact information for anyone we could contact in an effort to reach you.”

3. Contact Person 1

Name: _____ Relationship: _____
 Address: _____ How should we identify ourselves when we call?

 Phone # (____) _____ - _____ Home
 (____) _____ - _____ Work
 (____) _____ - _____ Cell

4. Contact Person 2

Name: _____ Relationship: _____
 Address: _____ How should we identify ourselves when we call?

 Phone # (____) _____ - _____ Home
 (____) _____ - _____ Work
 (____) _____ - _____ Cell

5. Contact Person 3

Name: _____ Relationship: _____
 Address: _____ How should we identify ourselves when we call?

 Phone # (____) _____ - _____ Home
 (____) _____ - _____ Work
 (____) _____ - _____ Cell

Note: it is helpful to let participants know about times when study personnel will be in the ED and how the participant can reach us. Tell the participant that she can call the ED and ask to speak with someone from the “SHIP Project.” Encourage participants to call or drop in with new contact information or to check in at any time by calling the study hotline number 215-573-3055.

Participant Name: _____ (REMOVE)
Last First Middle I.

Study ID: _____

Group Assignment: NCCG ACG BIG (Notify Study Social Worker)

Enrollment Date: ____/____/____ Enrolling RA (name): _____

EN: _____ Recruited during off-hours via provider referral? Yes No

MRN: _____ (REMOVE)

Date of birth: ____/____/____

Demographic information (to be collected from ALL study participants through verbal interview):

1. How tall are you? _____ HEIGHT IN INCHES ***INTERVIEWER USE INCHES ONLY**

2. How much do you weigh? _____ WEIGHT IN POUNDS

3. What is your current legal marital status?

- 1 Single
- 2 Married
- 3 Divorced
- 4 Separated
- 5 Widowed

4. What is your current relationship or dating status? (Select 1 option and follow skip patterns).

- 1 Single, not dating →Skip to question 7
- 2 Single and dating (but not in a serious committed relationship) → Skip to question 7
- 3 Off-and-On relationship with a single partner (e.g., mostly together but with some breaks) } →
- 4 Committed relationship with a single partner } →
- 5 Other (specify): _____

↓ & Continue to question 5

4a. Is this the [Index Partner]?

0 No

1 Yes

→ Continue to question 5

5. How long has this relationship been going on? (if off-and-on, note from beginning to current) _____

Circle: days weeks months years

6. Are you currently living with your romantic/dating partner/spouse?

- 0 No
- 1 Yes
- 2 Off and On

7. Is your [Index partner] a:

- 1 Male
- 2 Female
- 3 Neither (does not identify as male or female) or Transgender

8. Who lives in your household? *Interviewer, check all that apply:* **OR** **Check here if participant LIVES ALONE**
- Partner/Ex-Partner Siblings Parents Other non-family members
- Children (yours or others') Other family members Communal living (treatment facility, shelter, etc.)
9. How many children under age 18 are in your household? (May or may not be your own children) _____
10. Are you currently employed?
- 0 No
- 1 Yes
- 2 Disabled
- 3 Retired
- 4 Full-time childcare/homemaker
11. Are you currently in a school or vocational training program?
- 0 No
- 1 Yes
12. What is the highest level of education that you have completed?
- 1 Less than high school
- 2 Some high school (didn't graduate)
- 3 High school graduate or GED
- 4 Some college/No degree (Includes vocational or certificate training)
- 5 College graduate (baccalaureate)
- 6 Some postgraduate education (graduate school)
- 7 Completed graduate degree
13. For statistical purposes, what was your approximate total household income for the past year, including income from all sources for any family members living with you:
- Interviewer directions: show respondent card.*
- | | |
|---------------------|----------------------|
| 1 Under \$10,000 | 5 \$25,000 - 34,999 |
| 2 \$10,000 - 14,999 | 6 \$35,000 - 49,999 |
| 3 \$15,000 - 19,999 | 7 \$50,000 - 99,999 |
| 4 \$20,000 - 24,999 | 8 \$100,000 and over |
14. Is your ethnic identification Hispanic/Latino?
- 0 No
- 1 Yes
15. What is your racial identification?
- 1 African American, Black
- 2 White, Caucasian
- 3 Pacific Islander
- 4 Asian, Asian-American
- 5 Native American, American Indian, Alaska Native
- 6 More than one race/ethnicity (SPECIFY: _____)
- 7 Other (SPECIFY: _____)

Baseline Women's Health Interview
Department of Emergency Medicine, University of Pennsylvania

Study ID: _____

Group Assignment (circle): ACG BIG

Name of Index Partner: _____

Is Current Partner: Index Partner New Partner No current partner

Indicate Interview Method: Phone Face-to-Face

INTERVIEWER DIRECTIONS: PLEASE COMPLETE THE FOLLOWING.

Date of Interview ____/____/____

Day of the week (please circle): M T W Th F Sa Su

Interview time start ____:____ AM PM

Time interrupted (if needed) ____:____ AM PM

Time resumed ____:____ AM PM

Time finished ____:____ AM PM

Total time of interview _____ hours / minutes

Total interruptions _____

RA Interviewer _____

Please answer the following questions when the interview has been completed:

RA 1. The respondent's general understanding of the questions was: 1 2 3 4
Poor Fair Good Excellent

RA 2. How frank was the respondent? 1 2 3 4
Probably Somewhat Mostly Entirely
Not Frank Frank Frank Frank

Interviewer notes:

INTERVIEWER DIRECTIONS: For unanswered questions, please write the following codes to the left of the question number. If in doubt of code, feel free to provide explanation next to question.

DK - DON'T KNOW/UNKNOWN; WHEN A PARTICIPANT DOES NOT KNOW THE ANSWER TO A QUESTION.
(LEFT BLANK) – REFUSED OR NOT ANSWERED; WHEN A PARTICIPANT DOES NOT WANT TO ANSWER A QUESTION OR DUE TO CERTAIN CIRCUMSTANCES IS NOT ANSWERED.

Interviewer says: "This interview will take approximately 20-25 minutes. Remember you can ask to stop the interview at any time and do not have to answer any question you do not feel comfortable answering."

Your lifestyle has an important influence on your health. Lifestyle refers to the habits you have developed with regard to eating, exercise, sleep, your use of alcohol, drugs, or cigarettes and the amount of stress in your personal relationships. First, I have some general questions about your health. All of these questions refer to your health in the past 3 months but they do not include your visit today to the emergency department."

Self-Rated Health

1. Over the past 3 months, how would you say your health has been?
 - 1 Excellent
 - 2 Very Good
 - 3 Good
 - 4 Fair
 - 5 Poor

Pregnancy

2. Have you been pregnant in the last 3 months?
 - 0 No
 - 2 Maybe/not sure
 - 1 Yes
 - 2a. If yes: What is the outcome/status of that pregnancy?
 - 1 Currently pregnant (gestational weeks: ____)
 - 2 Miscarriage/spontaneous abortion (gestational weeks: ____)
 - 3 Elective abortion (including for medical/health purposes)
 - 4 Live birth (gestational weeks: ____)

Diet Quality (GENACIS)

3. Which of the following best describes the quality of your diet?
 - 1 Very healthy
 - 2 Somewhat healthy
 - 3 Somewhat unhealthy
 - 4 Very unhealthy

Engagement in Treatment

4. During the past 3 months, how many times (not counting today) have you seen a health professional on an outpatient basis for: [if no visits in past 3 months, write 0]
 - 1 Medical problems? _____
 - 2 Psychiatric or mental health issues? _____ (e.g. therapist, social worker, psychiatrist)
 - 3 Problems (of your own) with drugs? _____
 - 4 Problems (of your own) with alcohol? _____
 - 5 Significant family problems? _____ (e.g. counselor, family specialist, social worker.)
5. During the past 3 months, how many times have you been hospitalized for:
 - 1 Medical problems? _____
 - 2 Psychiatric or mental health issues? _____
 - 3 Problems (of your own) with drugs? _____
 - 4 Problems (of your own) with alcohol? _____

Emergency care use/injury

6. During the past 3 months, how many times have you gone to the emergency room for yourself, not counting this visit? _____ **[if no prior ER visits in past 3 months, write 0]**

If patient had no prior emergency room visits in the last 3 months, skip to question 8

7. What were the reason(s) for your prior visit(s)? *(Indicate all that apply)*

_____ Injury _____ Medical (non-injury) _____ Ob/Gyn
_____ Mental Health _____ Drug / Alcohol

8. Including this visit, how many times in the last 3 months have you had injuries that required medical attention? _____
[if no significant injuries in past 3 months, write 0]

9. In the past 3 months, what is the TOTAL number of DAYS on which you were unable to do what was normally expected of you (e.g. work, childcare, household management) because of illness or injury? _____

Depression (CES-D10)

Interviewer says: "Now I'm going to ask you questions about how you have been feeling during the last 3 months. Please refer to the card [show card] to describe how often you have had the following problems in the last 3 months."

CARD READS: 0 Rarely or none of the time; less than one a day per week
 1 Some or little of the time; 1-2 days per week
 2 Occasionally or moderate amount of the time; 3-4 days per week
 3 Most or all of the time; 5-7 days per week

10. _____ I was bothered by things that usually don't bother me.

14. _____ I had trouble keeping my mind on what I was doing.

15. _____ I felt depressed.

16. _____ I felt that everything I did was an effort.

17. _____ I felt hopeful about the future.

18. _____ I felt fearful.

19. _____ My sleep was restless.

20. _____ I was happy.

22. _____ I felt lonely.

28. _____ I could not "get going."

Self-Efficacy (Generalized Scale)

Interviewer says: "Now I have some questions about how you deal with various life events. Please refer to the card [show card] to describe how true the following statements are of your experience over the past 3 months."

CARD READS: 1 Not at all true
 2 A little true
 3 Moderately true
 4 Exactly true

29. _____ I can always manage to solve difficult problems if I try hard enough.

30. _____ If someone opposes me, I can find the means and ways to get what I want.

31. _____ It is easy for me to stick to my aims and accomplish my goals.

32. _____ I am confident that I could deal efficiently with unexpected events.
33. _____ Thanks to my resourcefulness, I know how to handle unforeseen situations.
34. _____ I can solve most problems if I invest the necessary effort.
35. _____ I can remain calm when facing difficulties because I can rely on my coping abilities.
36. _____ When I am confronted with a problem, I can usually find several solutions.
37. _____ If I am in trouble, I can usually think of a solution.
38. _____ I can usually handle whatever comes my way.
39. _____ I am able to adapt when changes occur.
40. _____ I tend to bounce back after illness, injury or other hardships.

Social Support (Chicago Women's Health Risk Study - SHS)

Interviewer says: "Now I'll be asking you about the supports you have in your life. Please answer yes or no."

41. Do you have someone you can talk to about any problem?
- 0 No
- 1 Yes
42. Do you have someone you could stay with if needed?
- 0 No
- 1 Yes
43. Do you have someone you could borrow money from if needed?
- 0 No
- 1 Yes

Quality of life (WHO)

Interviewer says: "Now I have some questions about how you feel about your life overall."

44. How would you rate your quality of life?
- 1 Very good
- 2 Good
- 3 Neither good nor poor
- 4 Poor
- 5 Very poor
45. How much do you enjoy life?
- 1 Extremely
- 2 Very much
- 3 Moderately
- 4 A little
- 5 Not at all
46. How safe do you feel in your daily life?
- 1 Extremely
- 2 Very much
- 3 Moderately
- 4 A little
- 5 Not at all

Health Behaviors (GENACIS)

Interviewer says: "Now I'll be asking you questions about your health habits in the last 3 months."

47. How many days per week do you engage in vigorous physical exercise (15 minutes duration or more), such as walking briskly, running, bicycling, swimming)? _____
48. In the past 3 months have you been dieting to lose weight?
- 0 No
 - 1 Yes
49. In the past 3 months have you used any tobacco products?
- 0 No
 - 1 Yes
- a. On average, how many cigarettes/cigar/pipe/pinch do you smoke/use each day? **[20 cigarettes/pack]**
- 1 1-9
 - 2 10-19
 - 3 20-29
 - 4 30 or more
50. In the past 3 months, on average, how many hours of sleep have you gotten each night? _____
51. In the past 3 months, how often have you had difficulty getting to sleep?
- 1 Never
 - 2 Rarely
 - 3 Sometimes
 - 4 Often

Timeline Follow Back (TLFB) Script and Calendar)

Interviewer Directions: Provide participant with Timeline Follow Back Calendar. Circle today's date and the date 12 weeks back. The respondent will be answering questions within this three month timeframe. For emphasis, it may be useful "cross out" preceding months. The participant will use this calendar to record the number of drinks consumed each day as well as usual or unusual monthly drinking patterns throughout the past three months. Using the following script you will prompt respondents to think about their drinking with respect to national holidays, personal "special" days (i.e. birthdays), and regular drinking patterns (often centered around specific weekly events). Be sure to attach completed TLFB Calendar to the completed interview.

Interviewer script: "Now I'm going to ask you some questions about how much alcohol you've had to drink the last 3 months (12 weeks; 84 days). This includes the time period between:

START DATE: ____/____/____ & **END DATE:** ____/____/____ (yesterday).

"We would first like you to reconstruct your drinking for the past 3 months prior to today. This is not a difficult task, especially when you use an actual calendar, like this one (Show calendar). The idea is to record the number of drinks you consumed on each day for the past 3 months. The way we want you to record your drinking of the calendar is to use standard drinks. The top of this calendar shows what a standard drink is. So what type of alcoholic beverage do you typically drink?" (If specific beverage, circle on calendar and record here: _____)

"If you had 6 _____ (insert typical beverage) on a given day you would write down the number 6. Also as you can see, holidays are listed on the calendar to help you recall your drinking (Use Calendar to indicate examples). "When you fill out the calendar, we realize that it is hard to recall things with 100% accuracy, but give us your best estimate. Let's begin with today (Circle today's date on calendar) and go back 3 months (Circle day on calendar and block out months before/ after if necessary).

"Sometimes if you think about various times of the month or special days that occurred during the past three months, it can also help you to fill out the calendar. For instance, did you take any vacations during the past three months?"

Interviewer should now prompt a participant's recall by mentioning the following:

- Vacations
- Weddings/birthdays
- Pay days
- Certain days of the week: every Thursday when playing cards
- Seasonal: around the holidays

Data Entry Directions: After the interview is complete, be sure to attach a completed calendar to the WHI. When we enter data into the database, we will **enter the start date and end date and the number of drinks consumed on day 1 (start date) through day 84 (end date) – so make sure your calendar is legible!**

Intoxication Question (GENACIS)

Interviewer says: "Thank you for spending some time answering questions about your drinking. I just have one additional question about your use of alcoholic beverages during the last 3 months. Please use this card [SHOW CARD] as a reference."

52. About how often in the last 3 months did you drink enough to feel drunk—that is, where drinking noticeably affected your thinking, talking and behavior?

- 0 Never
- 1 Less than Monthly
- 2 Monthly
- 3 Weekly
- 4 Daily or Almost Daily

Partner's Drinking (GENACIS)

Interviewer says: "Now I'm going to ask you some questions about your INDEX partner's drinking."

53. In the past 3 months, how often has YOUR INDEX PARTNER had a drink containing alcohol?

1 Never

53a. If never: Has your partner ever had a drinking problem?

0 No

1 Yes, in recovery now

→ **IF NEVER, after asking 53a, skip to question 56**

2 Monthly or less

3 2 to 4 times a month

4 2 to 3 times a week

5 4 or more times a week

54. In the past 3 months, how many drinks does YOUR INDEX PARTNER have on a typical day when he/she is drinking?

1 1 or 2

2 3 or 4

3 5 or 6

4 7 to 9

5 10 or more standard drinks

55. In the past 3 months, how often has YOUR INDEX PARTNER had **[4 if partner is female, 5 if male]** or more drinks on one occasion?

1 Never

2 Less than monthly

3 Monthly

4 Weekly

5 Daily or almost daily

56. During the last 3 months, how much of your drinking has been with your [INDEX] partner?

1 All or almost all occasions

2 Most occasions

3 Some occasions

4 A few occasions

5 Never

57. In the past 3 months, when you and your partner quarreled, about how often has your [INDEX] partner been drinking?
[Show Card if Possible]

1 All of the time

2 Most of the time

3 More often than not

4 Occasionally

5 Rarely

6 Never

7 Partner does not drink

58. In the past 3 months, when you and your [INDEX] partner quarreled, about how often have you been drinking?
[Show Card if Possible]

- 1 All of the time
- 2 Most of the time
- 3 More often than not
- 4 Occasionally
- 5 Rarely
- 6 Never
- 7 I do not drink

Supplementary Drug Use (GENACIS)

Interviewer says: "I'm going to read you a list of questions about your potential involvement with drugs other than alcohol and tobacco during the past 3 months. When I say 'drug abuse' I mean the use of illegal drugs and the inappropriate or misuse of prescribed or over-the-counter medications. Remember, these questions refer to the past 3 months."

59. In the past 3 months, have you used marijuana?

- 0 No
- 1 Yes

59a. If yes, how often have you used marijuana in the past 3 months?

- 0 Never
- 1 Less than once a week (1-3 times)
- 2 About once a week (4-5 times)
- 3 More than once a week but not every day
- 4 Daily or almost daily

60. In the past 3 months, has your [INDEX] partner used marijuana?

- 0 No
- 1 Yes

61. In the past 3 months, have you used street drugs other than marijuana?

- 0 No
- 1 Yes

61a. If yes, which street drugs have you used in the past 3 months?

Solvents Tranquilizers (e.g. Valium) Barbituates (e.g. downers)
 Cocaine Stimulants (e.g. Speed) Hallucinogens (e.g. LSD)
 Narcotics (e.g. Heroin) Other _____

62. In the past 3 months, have you taken any prescription drugs that were not prescribed for you – or taken the drug in a manner that was not prescribed?

- 0 No
- 1 Yes

62a. If yes, which drugs? _____

63. In the past 3 months, has your [INDEX] partner used street drugs (not including marijuana) or prescription drugs?

- 0 No
- 1 Yes

Relationship Satisfaction (Dyadic Adjustment Scale)

Interviewer says: "Now I'm going to ask you about your intimate relationships. That is, a sexual or romantic relationship with a boy/girlfriend, spouse, partner, lover, etc. I'd like you to answer these questions based on a relationship that you are in currently, or, if you are not currently in a relationship, about the person with whom you were most recently in a relationship."

64. The following numbers represent different degrees of happiness in your relationship. The middle point, "happy," represents the degree of happiness of most relationships. Please indicate the number which best describes the degree of happiness, all things considered, in your relationship. **[Show Card if Possible]**

0	1	2	3	4	5	6
Extremely Unhappy	Fairly Unhappy	A Little Unhappy	Happy	Very Happy	Extremely Happy	Perfectly Happy

65. When answering this question, were you thinking of a relationship with [Index Partner's name] or a partner other than the INDEX partner?

- 1 Index Partner
- 2 New Partner / Partner other than INDEX partner

If person answers this question referencing a partner other than the INDEX partner, complete 65a.

65a. If you were not thinking of the INDEX partner, I'd like for you to now answer this question based on your former relationship with the INDEX partner.

The middle point, "happy," represents the degree of happiness of most relationships. Please indicate the number which best describes the degree of happiness, all things considered, in your former relationship with the INDEX partner. **[Show Card if Possible]**

0	1	2	3	4	5	6
Extremely Unhappy	Fairly Unhappy	A Little Unhappy	Happy	Very Happy	Extremely Happy	Perfectly Happy

IPV Severity (CAS Assessment)

Interview says: "The next few questions will ask about your relationship. They are a series of related questions and therefore, some questions may seem repetitive."

"We would like to know if you have had any of the experiences listed below with your previous and/or current partner. Please tell me how many times in the PAST 3 MONTHS that you experienced these actions using the following scale:"

SCALE:

0	1	2	3	4	5
Never	Only Once	Several Times	Once/ Month	Once/ Week	Daily

Actions	How often it happened					
	Never	Only Once	Several Times	Once/ Month	Once/ Week	Daily
66. Told me that I wasn't good enough	0	1	2	3	4	5
67. Kept me from medical care	0	1	2	3	4	5
68. Followed me	0	1	2	3	4	5
69. Tried to turn my family, friends and children against me	0	1	2	3	4	5
70. Locked me in the bedroom	0	1	2	3	4	5
71. Slapped me	0	1	2	3	4	5
72. Forced me to have sex	0	1	2	3	4	5
73. Told me that I was ugly	0	1	2	3	4	5
74. Tried to keep me from seeing or talking to my family	0	1	2	3	4	5

Actions	How often it happened					
	Never	Only Once	Several Times	Once/ Month	Once/ Week	Daily
75. Threw me	0	1	2	3	4	5
76. Hung around outside my house	0	1	2	3	4	5
77. Blamed me for causing their violent behavior	0	1	2	3	4	5
78. Harassed me over the telephone	0	1	2	3	4	5
79. Shook me	0	1	2	3	4	5
80. Tried to force me to have sex	0	1	2	3	4	5
81. Harassed me at work	0	1	2	3	4	5
82. Pushed, grabbed or shoved me	0	1	2	3	4	5
83. Used a knife or gun or other weapon	0	1	2	3	4	5
84. Became upset if dinner/housework wasn't done	0	1	2	3	4	5
85. Told me that I was crazy	0	1	2	3	4	5
86. Told me that no one would ever want me	0	1	2	3	4	5
87. Took my wallet and left me stranded	0	1	2	3	4	5
88. Hit or tried to hit me with something	0	1	2	3	4	5
89. Did not want me to socialize with my female friends	0	1	2	3	4	5
90. Put foreign objects in my vagina	0	1	2	3	4	5
91. Refused to let me work outside the home	0	1	2	3	4	5
92. Kicked me, bit me or hit me with a fist	0	1	2	3	4	5
93. Tried to convince my friends, family or children that I was crazy	0	1	2	3	4	5
94. Told me that I was stupid	0	1	2	3	4	5
95. Beat me up	0	1	2	3	4	5

IPV Severity (WEB Assessment)

Directions: Please remember to adjust the nouns/pronouns depending on the gender of the partner.

Interview says: "The following are a number of statements that women have used to describe their lives with their partners. Please tell me how much you agree or disagree with each statement, with regard to your relationship with [Index Partner's Name], using the following scale:"

SCALE: **[Show Card if Possible]**

1	2	3	4	5	6
Disagree	Disagree	Disagree	Agree	Agree	Agree
Strongly	Somewhat	A Little	A Little	Somewhat	Strongly

96. He makes me feel unsafe even in my own home.	1	2	3	4	5	6
97. I feel ashamed of the things he does to me.	1	2	3	4	5	6
98. I try not to rock the boat because I am afraid of what he might do.	1	2	3	4	5	6
99. I feel like I am programmed to react a certain way to him.	1	2	3	4	5	6
100. I feel like he keeps me prisoner.	1	2	3	4	5	6
101. He makes me feel like I have no control over my life, no power, no protection.	1	2	3	4	5	6
102. I hide the truth from others because I am afraid not to.	1	2	3	4	5	6

103.	I feel owned and controlled by him.	1	2	3	4	5	6
104.	He can scare me without laying a hand on me.	1	2	3	4	5	6
105.	He has a look that goes straight through me and terrifies me.	1	2	3	4	5	6

IPV Severity (Danger Assessment)

Directions: Please remember to adjust the nouns/pronouns depending on the gender of the partner.

Interviewer says: "For the following questions, please answer YES or NO, with regard to [INDEX Partner's Name]"

		YES	NO
106.	Has the physical violence increased in severity or frequency over the past year?	1	0
107.	Does he own a gun?	1	0
108.	Have you left him after living together during the past year? (if you have never lived with him, check here ____)	1	0
109.	Is he unemployed?	1	0
110.	Has he ever used a weapon against you or threatened you with a lethal weapon? (if yes, was the weapon a gun?____)	1	0
111.	Does he threaten to kill you?	1	0
112.	Has he avoided being arrested for domestic violence?	1	0
113.	Do you have a child that is not his?	1	0
114.	Has he ever forced you to have sex when you did not wish to do so?	1	0
115.	Does he ever try to choke you?	1	0
116.	Does he use illegal drugs? (By drugs, I mean "uppers" or amphetamines, speed, angel dust, cocaine, "crack", street drugs or mixtures; not marijuana)	1	0
117.	Is he an alcoholic or problem drinker?	1	0
118.	Does he control most or all of your daily activities? (For instance: does he tell you who you can be friends with, when you can see your family, how much money you can use, or when you can take the car?) (if he tries, but you do not let him, check here:____)	1	0
119.	Is he violently and constantly jealous of you?	1	0
120.	Have you ever been beaten by him while you were pregnant? (if you have never been pregnant with him, check here:____)	1	0
121.	Has he ever threatened or tried to commit suicide?	1	0
122.	Does he threaten to harm your children?	1	0
123.	Do you believe he is capable of killing you?	1	0
124.	Does he follow or spy on you, leave threatening notes or voicemail messages, destroy your property, or call you when you don't want him to?	1	0
125.	Have you ever threatened or tried to commit suicide? (if yes, are you currently feeling that way? ____)	1	0

NOTE: If current Suicidal Ideation, notify provider. Patient is still enrolled in study since she has already been randomized.

PTSD (Primary Care PTSD Screen)

Interviewer says: "Have you ever had any experience in your life that was so frightening, horrible, or upsetting that, in the past 3 months, you:"

126.	Have had nightmares about it or thought about it when you did not want to?	1 Yes	0 No
127.	Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?	1 Yes	0 No
128.	Were constantly on guard, watchful, or easily startled?	1 Yes	0 No
129.	Felt numb or detached from others, activities, or your surroundings?	1 Yes	0 No

Sexual Abuse History (GENACIS)

130. When you were growing up, did someone try to make you do sexual things or watch sexual things? This could be by a family member or someone other than a family member.

0 No

1 Yes

130a. **If Yes**, did this happen before you were 16 years old (age 15 or younger)?

0 No

1 Yes

131. Did you feel that you were sexually abused when you were growing up? This could be by a family member or someone other than a family member.

0 No

1 Yes

Arrest History

132. In the last 3 months, has your [INDEX] partner been arrested for anything?

0 No

1 Yes (If yes, on what charges? _____)

133. In the last 3 months, have you been arrested for anything?

0 No

1 Yes (If yes, on what charges? _____)

Engagement with agencies/support

Interviewer says: "Now I have some questions about you and your [INDEX] partner's use of supportive services."

134. In the last 3 months, have YOU used any police or court services because of family violence? (Such as calling the police, meeting with a detective or prosecutor, going to family court, for divorce or custody, or applying for an order of protection?)

0 No

1 Yes (If yes, describe: _____)

135. In the last 3 months, have you used any domestic violence services, including shelter, legal services, counseling, or support group services?

0 No

1 Yes (If yes, describe: _____)

136. In the last 3 months, have you used any supportive services for alcohol use (e.g. counseling, detox, AA)?

0 No

1 Yes (If yes, describe: _____)

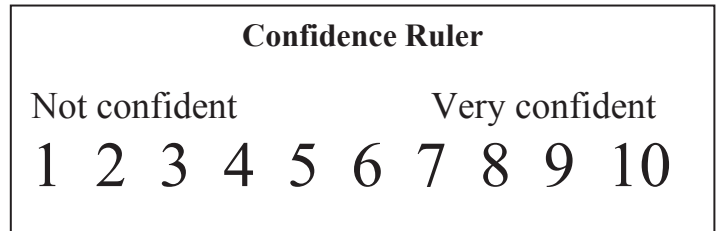
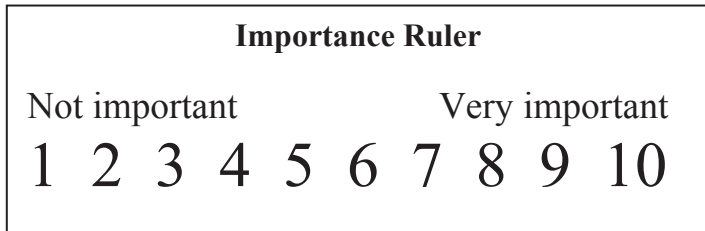
137. In the last 3 months, has your [INDEX] partner used any supportive services for alcohol use (e.g. counseling, detox, AA)?

0 No

1 Yes (If yes, describe: _____)

Motivation to Change (Importance / Confidence Rulers)

Interviewer says: "Please refer to importance and confidence scales [show card]. These questions refer to your romantic relationships in general." **[Show Card if Possible]**



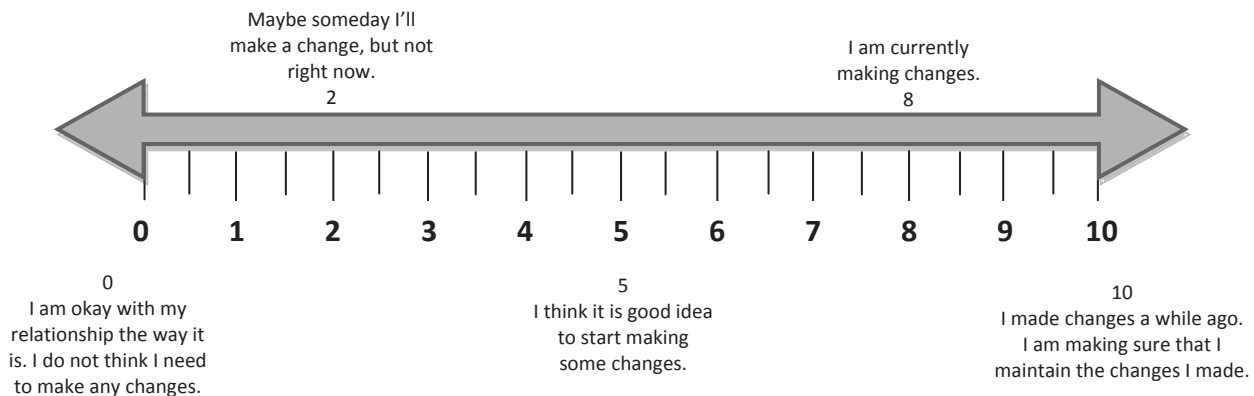
138. On a scale of 1-10, where 1 means "not at all important" and 10 means "very important," how important is it to you to take steps to change the level of conflict in your romantic relationships? _____

139. On a scale of 1-10, where 1 means "not at all confident" and 10 means "very confident," how confident are you - if you made a decision to change - that you could change the level of conflict in your romantic relationships? _____

140. On a scale of 1-10, where 1 means "not at all important" and 10 means "very important," how important is it to you to take steps to reduce your alcohol use? _____

141. On a scale of 1-10, where 1 means "not at all confident" and 10 means "very confident," how confident are you - if you made a decision to change - that you could reduce your alcohol use? _____

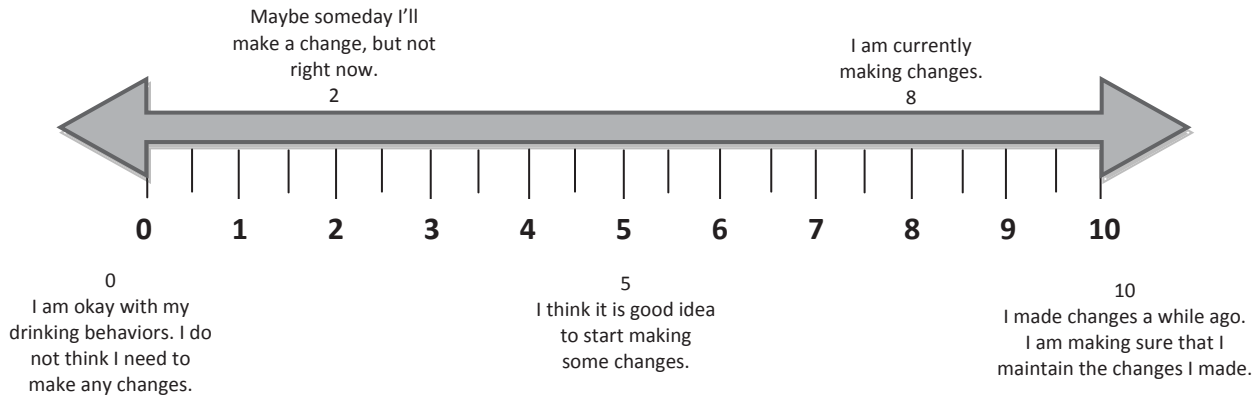
Readiness to Change - Relationship



Interviewer says: "Using this ruler, we would like you to choose a number between 0 and 10 to indicate how ready you are to make a change in your relationship with your [INDEX] partner. You can choose 0, "I am okay with my relationship the way it is. I do not think I need to make any changes" or 10, "I made changes a while ago. I am making sure that I maintain the changes I made" or any number in between. A score of 2 indicates: "maybe someday I'll make a change, but not right now", 5 indicates: "I think it is a good idea to start making changes", and 8 indicates: "I am currently making changes".

142. Please pick a number between 0 and 10 to indicate how ready you are to make changes in your relationship. _____

Readiness to Change – Drinking Behaviors



Interviewer says: “Using this ruler, we would like you to choose a number between 0 and 10 to indicate how ready you are to make a change in your drinking behaviors. You can choose 0, “I am okay with my drinking behaviors. I do not think I need to make any changes” or 10, “ I made changes a while ago. I am making sure that I maintain the changes I made” or any number in between. A score of 2 indicates: “maybe someday I’ll make a change, but not right now”, 5 indicates: “I think it is a good idea to start making changes”, and 8 indicates: “I am currently making changes”.

143. Please pick a number between 0 and 10 to indicate how ready you are to make a change in your drinking behaviors. _____

Record Scores of Eligibility Assessment

144. Patient’s total AUDIT score (collected on eligibility screening) _____

145. Patient’s total CTS2S score (collected during eligibility screening) _____

⇒ Referrals Given YES NO (REASON) _____

IMPORTANT INTERVIEWER NOTE: Remember to attach patient’s completed Eligibility Assessment & Completed Timeline Follow-back Calendar to this Interview!

INTERVIEWER DIRECTIONS: THANK THE SUBJECT FOR THEIR PARTICIPATION. IF PARTICIPANT IS IN BIG, REFER TO THERAPIST FOR MET INTERVENTION.

ACG & BIG Follow-up Women's Health Interview
Department of Emergency Medicine, University of Pennsylvania

Study ID: _____

Group Assignment (circle): ACG BIG

Name of Index Partner (copy from Baseline): _____

Indicate which Follow-Up WHI: 3 month follow-up 6 month follow-up 12 month follow-up

Indicate Interview Method: Phone Face-to-Face

INTERVIEWER DIRECTIONS: PLEASE COMPLETE THE FOLLOWING.

Date of Interview ____/____/_____

Day of the week (please circle): M T W Th F Sa Su

Interview time start ____:____ AM PM

Time interrupted (if needed) ____:____ AM PM

Time resumed ____:____ AM PM

Time finished ____:____ AM PM

Total time of interview _____ hours / minutes

Total interruptions _____

RA Interviewer _____

Please answer the following questions when the interview has been completed:

RA 1. The respondent's general understanding of the questions was:	1	2	3	4
	Poor	Fair	Good	Excellent

RA 2. How frank was the respondent?	1	2	3	4
	Probably Not Frank	Somewhat Frank	Mostly Frank	Entirely Frank

Interviewer notes:

INTERVIEWER DIRECTIONS: For unanswered questions, please write the following codes to the left of the question number. If in doubt of code, feel free to provide explanation next to question.

DK - DON'T KNOW/UNKNOWN; WHEN A PARTICIPANT DOES NOT KNOW THE ANSWER TO A QUESTION.
(LEFT BLANK) – REFUSED OR NOT ANSWERED; WHEN A PARTICIPANT DOES NOT WANT TO ANSWER A QUESTION OR DUE TO CERTAIN CIRCUMSTANCES IS NOT ANSWERED.

Interviewer Says: "This follow-up interview will take approximately 20-30 minutes. Remember you can ask to stop the interview at any time. Many of these questions will ask about your behaviors and feelings, as well as occurrences during the last 3 months; so the time period between (give approximate date 3 months back) and now. First, I just want to ask about any changes to your contact information or living situation since we last spoke."

1. Have there been any changes in your address or contact information since we last spoke?

0 No

1 Yes → If yes, please describe/update *****Be sure to update plan accordingly with new information.*****

2. The last time we spoke, we made a "safe contact plan" (what to do/say if it becomes unsafe to continue talking; how we should contact you and identify ourselves); I would like to review that with you now. [Review contact information] Do you need to change or update this plan at this time?

0 No

1 Yes → If yes, *****Be sure to update plan accordingly with new information.*****

3. Who do you live with? *Interviewer, check all that apply:* **OR** ___ **Check here if participant LIVES ALONE**

___ Partner (including ex-partner) ___ Siblings ___ Communal living (treatment

___ Children (yours or others') ___ Other family members facility, shelter, etc.)

___ Parents ___ Other non-family members

4. What is your current legal marital status?

1 Single

2 Married

3 Divorced

4 Separated

5 Widowed

5. What is your current relationship or dating status?

1 Single, not dating

5a. Have you had a partner in the last 3 months?

0 No

1 Yes... And was this [INDEX] partner? **Please Circle:** Yes No

2 Single and dating (but not in a serious committed relationship)

5b. Have you had a partner in the last 3 months?

0 No

1 Yes... And was this [INDEX] partner? **Please Circle:** Yes No

3 Off-and-On relationship with a single partner (e.g., mostly together but with some breaks)

5c. Is this the [Index] Partner?

0 No

1 Yes

4 Committed relationship with a single partner

5d. Is this the [Index] Partner?

0 No

1 Yes

5 Other (specify): _____

6. During the past 3 months have you had ongoing interactions with INDEX partner (e.g., trying to break up)?

- 0 No
- 1 Yes

7. **If participant is currently in a relationship:** Are you living with your romantic/dating partner/spouse?

- 0 No
- 1 Yes
- 2 Off and on
- 3 *Participant is not currently in a relationship*

8. How many children under age 18 are in your household? (May or may not be your own children) _____

9. Are you currently employed?

- 0 No
- 1 Yes
- 2 Disabled
- 3 Retired
- 4 Full-time child care/ homemaker

10. Have there been any major changes in your overall health in the last three months?

- 0 No
- 1 Yes. Please describe: _____

11. In the past three months, have you received any **new** medication?

- 0 No
- 1 Yes

11a. If yes, for what? (prompt and check all that apply):

- Medical Problem?

 Mental Health/Psychological/Emotional?
- Help stay off drugs?

 Help quit smoking?

 Help cut down/Stop drinking?
- Other (please specify) _____

Interviewer says: "Your lifestyle has an important influence on your health. Lifestyle refers to the habits you have developed with regard to eating, exercise, sleep, your use of alcohol, drugs, or cigarettes and the amount of stress in your personal relationships. All of these questions refer to your health in the past 3 months but they do not include your visit today to the emergency department."

Self-Rated Health

12. Over the past 3 months, how would you say your health has been?

- 1 Excellent
- 2 Very Good
- 3 Good
- 4 Fair
- 5 Poor

Pregnancy

13. Have you been pregnant in the last 3 months?

- 0 No
- 2 Maybe/not sure
- 1 Yes

13a. If yes: What is the outcome/status of that pregnancy?

- 1 Currently pregnant (gestational weeks: ____)
- 2 Miscarriage/spontaneous abortion (gestational weeks: ____)
- 3 Elective abortion (including for medical/health purposes)
- 4 Live birth (gestational weeks: ____)

Diet Quality (GENACIS)

14. Which of the following best describes the quality of your diet?

- 1 Very healthy
- 2 Somewhat healthy
- 3 Somewhat unhealthy
- 4 Very unhealthy

Engagement in Treatment

15. During the past 3 months, how many times (not counting today) have you seen a health professional on an outpatient basis for: **[if no visits in past 3 months, write 0]**

- 1 Medical problems? _____
- 2 Psychiatric or mental health issues? _____ (e.g. therapist, social worker, psychiatrist)
- 3 Problems (of your own) with drugs? _____
- 4 Problems (of your own) with alcohol? _____
- 5 Significant family problems? _____ (e.g. counselor, family specialist, social worker)

16. During the past 3 months, how many times have you been hospitalized for: **[if no visits in past 3 months, write 0]**

- 1 Medical problems? _____
- 2 Psychiatric or mental health issues? _____
- 3 Problems (of your own) with drugs? _____
- 4 Problems (of your own) with alcohol? _____

Emergency care use/injury

17. During the past 3 months, how many times have you gone to the emergency room for yourself? _____

[if no prior ER visits in past 3 months, write 0]

If patient had no prior emergency room visits in the last 3 months, skip to question 19

18. What were the reason(s) for your prior visit(s)? (*Indicate all that apply*)

- | | | |
|---------------------|----------------------------|--------------|
| _____ Injury | _____ Medical (non-injury) | _____ Ob/Gyn |
| _____ Mental Health | _____ Drug / Alcohol | |

19. How many times in the last 3 months have you had injuries that required medical attention? _____

[if no significant injuries in past 3 months, write 0]

20. In the past 3 months, what is the TOTAL number of DAYS you on which you were unable to do what was normally expected of you (e.g. work, childcare, household management) because of illness or injury? _____

Depression (CES-D10)

Interviewer says: "Now I'm going to ask you questions about how you have been feeling during the last 3 months. Please refer to the card [show card] to describe how often you have had the following problems in the last 3 months."

- CARD READS:
- | | |
|---|--|
| 0 | Rarely or none of the time; less than one a day per week |
| 1 | Some or little of the time; 1-2 days per week |
| 2 | Occasionally or moderate amount of the time; 3-4 days per week |
| 3 | Most or all of the time; 5-7 days per week |

21. _____ I was bothered by things that usually don't bother me.

25. _____ I had trouble keeping my mind on what I was doing.

26. _____ I felt depressed.

27. _____ I felt that everything I did was an effort.

28. _____ I felt hopeful about the future.

29. _____ I felt fearful.

30. _____ My sleep was restless.

31. _____ I was happy.

33. _____ I felt lonely.

39. _____ I could not "get going."

Self-Efficacy (Generalized Scale)

Interviewer says: "Now I have some questions about how you deal with various life events. Please describe how true the following statements are of your experience over the past 3 months, using the following scale." **[SHOW CARD IF POSSIBLE]**

- SCALE:
- | | |
|---|-----------------|
| 1 | Not at all true |
| 2 | A little true |
| 3 | Moderately true |
| 4 | Exactly true |

40. _____ I can always manage to solve difficult problems if I try hard enough.

41. _____ If someone opposes me, I can find the means and ways to get what I want.

42. _____ It is easy for me to stick to my aims and accomplish my goals.

43. _____ I am confident that I could deal efficiently with unexpected events.

44. _____ Thanks to my resourcefulness, I know how to handle unforeseen situations.

45. _____ I can solve most problems if I invest the necessary effort.

46. _____ I can remain calm when facing difficulties because I can rely on my coping abilities.

47. _____ When I am confronted with a problem, I can usually find several solutions.

48. _____ If I am in trouble, I can usually think of a solution.

49. _____ I can usually handle whatever comes my way.

50. _____ I am able to adapt when changes occur.

51. _____ I tend to bounce back after illness, injury or other hardships.

Social Support (Chicago Women's Health Risk Study - SHS)

Interviewer says: "Now I'll be asking you about the supports you have in your life. Please answer yes or no."

52. Do you have someone you can talk to about any problem?

- 0 No
- 1 Yes

53. Do you have someone you could stay with if needed?

- 0 No
- 1 Yes

54. Do you have someone you could borrow money from if needed?

- 0 No
- 1 Yes

Quality of life (WHO)

Interviewer says: "Now I have some questions about how you feel about your life overall."

55. How would you rate your quality of life?

- 1 Very good
- 2 Good
- 3 Neither good nor poor
- 4 Poor
- 5 Very poor

56. How much do you enjoy life?

- 1 Extremely
- 2 Very much
- 3 Moderately
- 4 A little
- 5 Not at all

57. How safe do you feel in your daily life?

- 1 Extremely
- 2 Very much
- 3 Moderately
- 4 A little
- 5 Not at all

Health Behaviors (GENACIS)

Interviewer says: "Now I'll be asking you questions about your health habits in the last 3 months."

58. How many days per week do you engage in vigorous physical exercise (15 minutes duration or more) (e.g., walking briskly, running, bicycling, swimming)? _____

59. In the past 3 months have you been dieting to lose weight?

- 0 No
- 1 Yes

60. In the past 3 months have you used any tobacco products?

- 0 No
1 Yes

a. On average, how many cigarettes/cigar/pipe/pinch do you smoke/use each day? **[20 cigarettes/pack]**

- 1 1-9
2 10-19
3 20-29
4 30 or more

61. In the past 3 months, on average, how many hours of sleep have you gotten each night? _____

62. In the last 3 months, how often have you had difficulty getting to sleep?

- 1 Never
2 Rarely
3 Sometimes
4 Often

AUDIT (Drinking)

Interviewer says: "Now I am going to ask you some questions about your use of alcohol." **[SHOW CARD IF POSSIBLE]**

	Questions	0	1	2	3	4
63.	How often do you have a drink containing alcohol?	Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 or more times a week
64.	How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
65.	How often do you have four or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
66.	How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
67.	How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
68.	How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
69.	How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
70.	How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
71.	Have you or someone else been injured as a result of your drinking?	No		Yes, but not in the last year		Yes, during the last year
72.	Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year

Timeline Follow Back (TLFB Script)**Interviewer Directions:**

IF IN PERSON, Provide participant with Timeline Follow Back Calendar. Circle today's date and the date 4 weeks back. The respondent will be answering questions within this one month timeframe. The participant will use this calendar to record the number of drinks consumed each day.

IF ON THE PHONE, Ask participant if they have a calendar they can use as a reference in order to complete the next set of questions. Tell participant the start and end dates and ask them to provide you with the number of drinks consumed each day. You should write their responses on the TLFB as they state them.

Using the following script you will prompt respondents to think about their drinking with respect to national holidays, personal "special" days (i.e. birthdays), and regular drinking patterns (often centered around specific weekly events). Be sure to attach completed TLFB Calendar to the completed interview.

Interviewer script: "Now I'm going to ask you some questions about how much alcohol you've had to drink over the last month (28 days). This includes the time period between:

START DATE: ____/____/____ & **END DATE:** ____/____/____ (yesterday).

"Sometimes if you think about various times of the month or special days that occurred during the past month, it can also help you to recall how much alcohol you've had to drink. Do you have a calendar available that you can use as a reference? For instance, did you take any vacations during the past thirty days?"

Interviewer should now prompt a participant's recall by mentioning the following:

- Vacations
- Weddings/birthdays
- Pay days
- Certain days of the week: every Thursday when playing cards
- Seasonal: around the holidays

Data Entry Directions: After the interview is complete, be sure to attach a completed calendar to the WHI. When we enter data into the database, we will **enter the start date and end date and the number of drinks consumed on day 1 (start date) through day 28 (end date) – so make sure your calendar is legible!**

Intoxication Question (GENACIS)

Interviewer says: "Thank you for spending time earlier answering questions about your drinking. I just have one additional question about your use of alcoholic beverages during the last 3 months." **[SHOW CARD IF POSSIBLE]**

73. About how often in the last 3 months did you drink enough to feel drunk—that is, where drinking noticeably affected your thinking, talking and behavior?

- 0 Never
- 1 Less than Monthly
- 2 Monthly
- 3 Weekly
- 4 Daily or Almost Daily

Partner's Drinking (GENACIS)

Check here if participant has not had a partner in the past 3 months and Skip to Question 80.

Interviewer says: "Now I'm going to ask you some questions about your current or most recent partner's drinking over the past 3 months."

74. In the past 3 months, how often has YOUR PARTNER had a drink containing alcohol?

1 Never

74a. If never: Has your partner ever had a drinking problem? → **IF NEVER, after Q. 74a, skip to question 77**

0 No

1 Yes, in recovery now

2 Monthly or less

3 2 to 4 times a month

4 2 to 3 times a week

5 4 or more times a week

75. In the past 3 months, how many drinks does YOUR PARTNER have on a typical day when he/she is drinking?

1 1 or 2

2 3 or 4

3 5 or 6

4 7 to 9

5 10 or more standard drinks

76. In the past 3 months, how often has YOUR PARTNER had (4 if partner is female, 5 if male) or more drinks on one occasion?

1 Never

2 Less than monthly

3 Monthly

4 Weekly

5 Daily or almost daily

77. During the last 3 months, how much of your drinking has been with your partner?

1 All or almost all occasions

2 Most occasions

3 Some occasions

4 A few occasions

5 Never

78. In the past three months, when you and your partner quarreled, about how often has your partner been drinking?
[SHOW CARD IF POSSIBLE]

1 All of the time

2 Most of the time

3 More often than not

4 Occasionally

5 Rarely

6 Never

7 *Partner does not drink*

79. In the past 3 months, when you and your partner quarreled, about how often have you been drinking?
[SHOW CARD IF POSSIBLE]

- 1 All of the time
- 2 Most of the time
- 3 More often than not
- 4 Occasionally
- 5 Rarely
- 6 Never
- 7 *I do not drink*

Supplementary Drug Use (GENACIS)

Interviewer says: "I'm going to read you a list of questions about your potential involvement with drugs other than alcohol and tobacco during the past 3 months. When I say 'drug abuse' I mean the use of illegal drugs and the inappropriate or misuse of prescribed or over-the-counter medications. These questions refer to the past 3 months."

80. In the past three months, have you used marijuana?

- 0 No
- 1 Yes

80a. If yes, in the past three months how many times have you used marijuana?

- 0 Never
- 1 Less than once a week (1-3 times)
- 2 About once a week (4-5 times)
- 3 More than once a week but not every day
- 4 Daily or almost daily

81. In the past three months, has your current or most recent partner used marijuana?

- 0 No
- 1 Yes
- 2 No partner in the past 3 months

82. In the past 3 months, have you used street drugs other than marijuana?

- 0 No
- 1 Yes

82a. If yes, which street drugs have you used in the past 3 months?

___ Solvents	___ Tranquilizers (e.g. Valium)	___ Barbituates (e.g. downers)
___ Cocaine	___ Stimulants (e.g. Speed)	___ Hallucinogens (e.g. LSD)
___ Narcotics (e.g. Heroin)	___ Other _____	

83. In the past 3 months, have you taken any prescription drugs that were not prescribed for you – or taken the drug a manner that was not prescribed?

- 0 No
- 1 Yes

83a. If yes, which drugs? _____

84. In the past 3 months, has your current or most recent partner used street drugs (not including marijuana) or prescription drugs?

- 0 No
- 1 Yes

Relationship Satisfaction (Dyadic Adjustment Scale)

Interviewer says: "Now I'm going to ask you about your intimate relationships. That is, a sexual or romantic relationship with a boy/girlfriend, spouse, partner, lover, etc. I'd like you to answer these questions based on a relationship that you are in currently, or, if you are not currently in a relationship, about the person with whom you were most recently in a relationship."

85. The following numbers represent different degrees of happiness in your relationship. The middle point, "happy," represents the degree of happiness of most relationships. Please circle the number which best describes the degree of happiness, all things considered, in your relationship. **[SHOW CARD IF POSSIBLE]**

0	1	2	3	4	5	6
Extremely Unhappy	Fairly Unhappy	A Little Unhappy	Happy	Very Happy	Extremely Happy	Perfectly Happy

IPV Severity (CTS2S)

Check here if participant has not had a partner in the past 3 months and Skip to Question 103.

Interviewer says: The next few questions will ask about your relationship. They are a series of related questions and therefore, some questions may seem repetitive."

"For the questions below, using the following scale, please tell me how many times in the past 3 MONTHS each of you did these things." **[SHOW CARD IF POSSIBLE]**

- | | |
|---|---|
| 0 = This has never happened | 4 = 6 - 10 times in the past 3 MONTHS |
| 1 = Once in the past 3 MONTHS | 5 = 11 - 20 times in the past 3 MONTHS |
| 2 = Twice in the past 3 MONTHS | 6 = More than 20 times in the past 3 MONTHS |
| 3 = 3 - 5 times in the past 3 MONTHS | P = Did NOT happen in the past 3 MONTHS, but it did happen before. |

86. I insulted or swore or shouted or yelled at my partner.	0	1	2	3	4	5	6	P
87. My partner insulted or swore or shouted or yelled at me.	0	1	2	3	4	5	6	P
88. I had a sprain, bruise, or small cut, or felt pain the next day because of a fight with my partner.	0	1	2	3	4	5	6	P
89. My partner had a sprain, bruise, or small cut, or felt pain the next day because of a fight with me.	0	1	2	3	4	5	6	P
90. I pushed, shoved, or slapped my partner.	0	1	2	3	4	5	6	P
91. My partner pushed, shoved, or slapped me.	0	1	2	3	4	5	6	P
92. I punched, kicked, or beat-up my partner.	0	1	2	3	4	5	6	P
93. My partner punched, kicked, or beat-me-up.	0	1	2	3	4	5	6	P
94. I destroyed something belonging to my partner or threatened to hit my partner.	0	1	2	3	4	5	6	P
95. My partner destroyed something belonging to me or threatened to hit me.	0	1	2	3	4	5	6	P
96. I went to see a doctor or needed to see a doctor because of a fight with my partner.	0	1	2	3	4	5	6	P
97. My partner went to see a doctor or needed to see a doctor because of a fight with me.	0	1	2	3	4	5	6	P
98. I used force (like hitting, holding down, or using a weapon) to make my partner have sex.	0	1	2	3	4	5	6	P

99.	My partner used force (like hitting, holding down, or using a weapon) to make me have sex.	0	1	2	3	4	5	6	P
100.	I insisted on sex when my partner did not want to or insisted on sex without a condom (but did not use physical force).	0	1	2	3	4	5	6	P
101.	My partner insisted on sex when I did not want to or insisted on sex without a condom (but did not use physical force).	0	1	2	3	4	5	6	P

IPV Severity (CAS Assessment)

Interview says: "We would like to know if you have had any of the experiences listed below with your previous and/or current partner. Please tell me how many times in the PAST 3 MONTHS that you experienced these actions using the following scale:"
[SHOW CARD IF POSSIBLE]

SCALE:

0	1	2	3	4	5
Never	Only Once	Several Times	Once/ Month	Once/ Week	Daily

Actions	How often it happened						
	Never	Only Once	Several Times	Once/ Month	Once/ Week	Daily	
102.	Told me that I wasn't good enough	0	1	2	3	4	5
103.	Kept me from medical care	0	1	2	3	4	5
104.	Followed me	0	1	2	3	4	5
105.	Tried to turn my family, friends and children against me	0	1	2	3	4	5
106.	Locked me in the bedroom	0	1	2	3	4	5
107.	Slapped me	0	1	2	3	4	5
108.	Forced me to have sex	0	1	2	3	4	5
109.	Told me that I was ugly	0	1	2	3	4	5
110.	Tried to keep me from seeing or talking to my family	0	1	2	3	4	5
111.	Threw me	0	1	2	3	4	5
112.	Hung around outside my house	0	1	2	3	4	5
113.	Blamed me for causing their violent behavior	0	1	2	3	4	5
114.	Harassed me over the telephone	0	1	2	3	4	5
115.	Shook me	0	1	2	3	4	5
116.	Tried to force me to have sex	0	1	2	3	4	5
117.	Harassed me at work	0	1	2	3	4	5
118.	Pushed, grabbed or shoved me	0	1	2	3	4	5
119.	Used a knife or gun or other weapon	0	1	2	3	4	5
120.	Became upset if dinner/housework wasn't done	0	1	2	3	4	5
121.	Told me that I was crazy	0	1	2	3	4	5
122.	Told me that no one would ever want me	0	1	2	3	4	5
123.	Took my wallet and left me stranded	0	1	2	3	4	5
124.	Hit or tried to hit me with something	0	1	2	3	4	5
125.	Did not want me to socialize with my female friends	0	1	2	3	4	5
126.	Put foreign objects in my vagina	0	1	2	3	4	5
127.	Refused to let me work outside the home	0	1	2	3	4	5
128.	Kicked me, bit me or hit me with a fist	0	1	2	3	4	5
129.	Tried to convince my friends, family or children that I was crazy	0	1	2	3	4	5
130.	Told me that I was stupid	0	1	2	3	4	5

Actions	How often it happened					
	Never	Only Once	Several Times	Once/ Month	Once/ Week	Daily
131. Beat me up	0	1	2	3	4	5

PTSD (Primary Care PTSD Screen)

Interviewer says: "Have you ever had any experience in your life that was so frightening, horrible, or upsetting that, in the past 3 months, you:"

132.	Have had nightmares about it or thought about it when you did not want to?	1 Yes	0 No
133.	Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?	1 Yes	0 No
134.	Were constantly on guard, watchful, or easily startled?	1 Yes	0 No
135.	Felt numb or detached from others, activities, or your surroundings?	1 Yes	0 No

Arrest History

136. In the last 3 months, has your partner been arrested for anything?

- 0 No
 1 Yes (If yes, on what charges? _____)
 2 No partner in the past 3 months

137. In the last 3 months, have you been arrested for anything?

- 0 No
 1 Yes (If yes, on what charges? _____)

Engagement with agencies/support

Interviewer says: "Now I have some questions about you and your partner's use of supportive services."

138. In the last 3 months, have YOU used any police or court services because of family violence? (Such as calling the police, meeting with a detective or prosecutor, going to family court, for divorce or custody, or applying for an order of protection?)

- 0 No
 1 Yes (If yes, describe: _____)

139. In the last 3 months, have YOU used any domestic violence services, including shelter, legal services, counseling, or support group services?

- 0 No
 1 Yes (If yes, describe: _____)

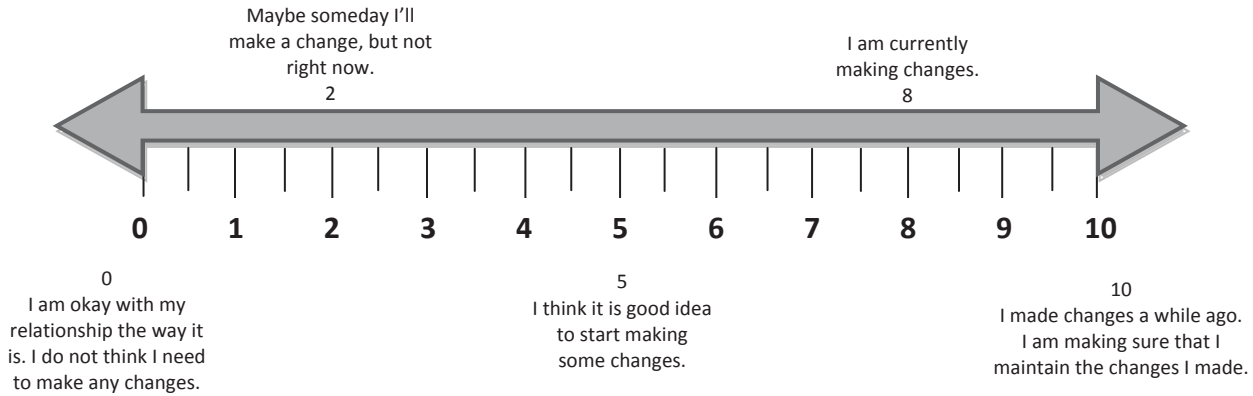
140. In the last 3 months, have YOU used any supportive services for alcohol use (e.g. counseling, detox, AA)?

- 0 No
 1 Yes (If yes, describe: _____)

141. In the last 3 months, has your PARTNER used any supportive services for alcohol use (e.g. counseling, detox, AA)?

- 0 No
 1 Yes (If yes, describe: _____)
 2 No partner in the past 3 months

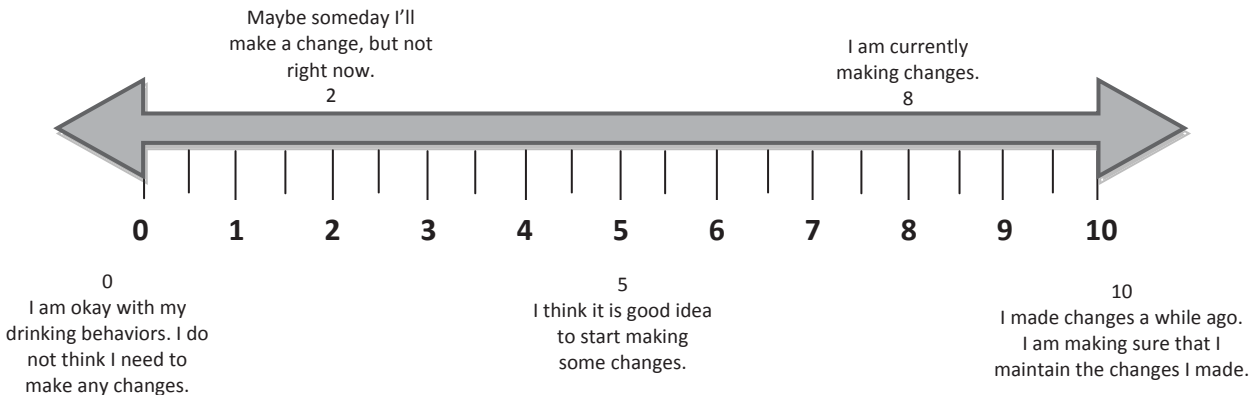
Readiness to Change - Relationship



Interviewer says: “Using this ruler, we would like you to choose a number between 0 and 10 to indicate how ready you are to make a change in your relationship with your [INDEX] partner. You can choose 0, “I am okay with my relationship the way it is. I do not think I need to make any changes” or 10, “I made changes a while ago. I am making sure that I maintain the changes I made” or any number in between. A score of 2 indicates: “maybe someday I’ll make a change, but not right now”, 5 indicates: “I think it is a good idea to start making changes”, and 8 indicates: “I am currently making changes”.

142. Please pick a number between 0 and 10 to indicate how ready you are to make changes in your relationship. _____

Readiness to Change – Drinking Behaviors



Interviewer says: “Using this ruler, we would like you to choose a number between 0 and 10 to indicate how ready you are to make a change in your drinking behaviors. You can choose 0, “I am okay with my drinking behaviors. I do not think I need to make any changes” or 10, “I made changes a while ago. I am making sure that I maintain the changes I made” or any number in between. A score of 2 indicates: “maybe someday I’ll make a change, but not right now”, 5 indicates: “I think it is a good idea to start making changes”, and 8 indicates: “I am currently making changes”.

143. Please pick a number between 0 and 10 to indicate how ready you are to make a change in your drinking behaviors. _____

Steps to Safety

144. Have you taken any steps in the past 3 months to increase your safety?

0 No

1 Yes

145a. What were they? (describe)

145. How satisfied are you with your participation in this study?

- 1 Extremely
- 2 Very
- 3 Somewhat
- 4 Not Very
- 5 Not at All

146. What impact, if any, has being in this study had on your level of safety? On a Scale of 1-5 from Safer to Less Safe, do you feel **[SHOW CARD IF POSSIBLE]**...

- | | | | | |
|-------|---|----------------|---|-----------|
| 1 | 2 | 3 | 4 | 5 |
| Safer | | About the same | | Less Safe |

147. What impact, if any, has being in this study had your drinking? On a Scale of 1-5 from Less to More, are you drinking **[SHOW CARD IF POSSIBLE]**...

- | | | | | |
|------|---|----------------|---|------|
| 1 | 2 | 3 | 4 | 5 |
| Less | | About the same | | More |

INTERVIEWER DIRECTIONS: THANK THE SUBJECT FOR THEIR PARTICIPATION IN THE STUDY!

IF THIS IS PARTICIPANT'S 3-MONTH OR 6-MONTH FOLLOW-UP WHI, REMIND THEM OF THEIR NEXT FOLLOW-UP WOMEN'S HEALTH INTERVIEW.

IF THIS IS AN ACG PARTICIPANT COMPLETING THEIR 12-MONTH (FINAL) WHI, BE SURE TO OFFER THE BRIEF HEALTH PROMOTION SESSION AT THIS TIME. THE SESSION CAN OCCUR IN PERSON AT THE ED OR OVER THE PHONE. PLEASE COMPLETE THE FOLLOWING:

⇒ Is the participant interested in receiving the intervention? YES NO

⇒ If No, please prompt for reason why not interested: _____

⇒ If Yes, preferred method: Phone In-Person

Inform MET Therapist, and tell participant: Someone will follow up with then in the next few days.

⇒ Referrals Given YES NO (REASON) _____

NCCG 3-month Women's Health Interview
Department of Emergency Medicine, University of Pennsylvania

Study ID: _____

Name of Index Partner: _____

Indicate Interview Method: Phone Face-to-Face

INTERVIEWER DIRECTIONS: PLEASE COMPLETE THE FOLLOWING.

Date of Interview ____/____/____

Day of the week (please circle): M T W Th F Sa Su

Interview time start ____:____ AM PM

Time interrupted (if needed) ____:____ AM PM

Time resumed ____:____ AM PM

Time finished ____:____ AM PM

Total time of interview _____ hours / minutes

Total interruptions _____

RA Interviewer _____

Please answer the following questions when the interview has been completed:

RA 1. The respondent's general understanding of the questions was:	1	2	3	4
	Poor	Fair	Good	Excellent

RA 2. How frank was the respondent?	1	2	3	4
	Probably Not Frank	Somewhat Frank	Mostly Frank	Entirely Frank

Interviewer notes:

INTERVIEWER DIRECTIONS: For unanswered questions, please write the following codes to the left of the question number. If in doubt of code, feel free to provide explanation next to question.

DK - DON'T KNOW/UNKNOWN; WHEN A PARTICIPANT DOES NOT KNOW THE ANSWER TO A QUESTION.

(LEFT BLANK) – REFUSED OR NOT ANSWERED; WHEN A PARTICIPANT DOES NOT WANT TO ANSWER A QUESTION OR DUE TO CERTAIN CIRCUMSTANCES IS NOT ANSWERED.

Interviewer Says: "This interview will take approximately 20-30 minutes. Remember you can ask to stop the interview at any time. Many of these questions will ask about your behaviors and feelings, as well as occurrences during the last 3 months; so the time period between (give approximate date 3 months back) and now. First, I just want to ask about any changes to your contact information or living situation since we last spoke."

1. Have there been any changes in your address or contact information since we last spoke?
 - 0 No
 - 1 Yes If yes, *****Be sure to update safe contact plan accordingly with new information.*****
2. The last time we spoke, we made a "safe contact plan" (what to do/say if it becomes unsafe to continue talking; how we should contact you and identify ourselves); I would like to review that with you now. [Review contact information] Do you need to change or update this plan at this time?
 - 0 No
 - 1 Yes If yes, *****Be sure to update safe contact plan accordingly with new information.*****
3. Who do you live with? *Interviewer, check all that apply:* **OR** **Check here if LIVES ALONE**

<input type="checkbox"/> Partner (including ex-partner)	<input type="checkbox"/> Siblings	<input type="checkbox"/> Communal living (treatment facility, shelter, etc.)
<input type="checkbox"/> Children (yours or others')	<input type="checkbox"/> Other family members	
<input type="checkbox"/> Parents	<input type="checkbox"/> Other non-family members	
4. What is your current legal marital status?
 - 1 Single
 - 2 Married
 - 3 Divorced
 - 4 Separated
 - 5 Widowed
5. What is your current relationship or dating status?
 - 1 Single, not dating
 - 5a. Have you had a partner in the last 3 months?
 - 0 No
 - 1 Yes... And was this [INDEX] partner? **Please Circle:** Yes No
 - 2 Single and dating (but not in a serious committed relationship)
 - 5b. Have you had a partner in the last 3 months?
 - 0 No
 - 1 Yes... And was this [INDEX] partner? **Please Circle:** Yes No
 - 3 Off-and-On relationship with a single partner (e.g., mostly together but with some breaks)
 - 5c. Is this the [Index] Partner?
 - 0 No
 - 1 Yes
 - 4 Committed relationship with a single partner
 - 5d. Is this the [Index] Partner?
 - 0 No
 - 1 Yes
 - 5 Other (specify): _____
6. During the past 3 months have you had ongoing interactions with [Index Partner] (e.g., trying to break up)?
 - 0 No
 - 1 Yes

7. **If participant is currently in a relationship:** Are you living with your romantic/dating partner/spouse?

- 0 No
- 1 Yes
- 2 Off and on
- 3 *Participant is not currently in a relationship*

8. How many children under age 18 are in your household? (May or may not be your own children)

9. Are you currently employed?

- 0 No
- 1 Yes
- 2 Disabled
- 3 Retired
- 4 Full-time child care / homemaker

10. Have there been any major changes in your overall health in the last three months?

- 0 No
- 1 Yes. Please describe: _____

11. In the past three months, have you received any **new** medication?

- 0 No
- 1 Yes

11a. If yes, for what? (prompt and check all that apply):

- Medical Problem? Mental Health/Psychological/Emotional?
- Help stay off drugs? Help quit smoking? Help cut down/Stop drinking?
- Other (please specify) _____

Interviewer says: "Your lifestyle has an important influence on your health. Lifestyle refers to the habits you have developed with regard to eating, exercise, sleep, your use of alcohol, drugs, or cigarettes and the amount of stress in your personal relationships. All of these questions refer to your health in the past 3 months but they do not include your visit today to the emergency department."

Self-Rated Health

12. Over the past 3 months, how would you say your health has been?

- 1 Excellent
- 2 Very Good
- 3 Good
- 4 Fair
- 5 Poor

Pregnancy

13. Have you been pregnant in the last 3 months?

- 0 No
- 2 Maybe/not sure
- 1 Yes

13a. If yes: What is the outcome/status of that pregnancy?

- 1 Currently pregnant (gestational weeks: ____)
- 2 Miscarriage/spontaneous abortion (gestational weeks: ____)
- 3 Elective abortion (including for medical/health purposes)
- 4 Live birth (gestational weeks: ____)

Diet Quality (GENAICS)

14. Which of the following best describes the quality of your diet?

- 1 Very healthy
- 2 Somewhat healthy
- 3 Somewhat unhealthy
- 4 Very unhealthy

Engagement in Treatment

15. During the past 3 months, how many times (not counting today) have you seen a health professional on an outpatient basis for: **[if no visits in past 3 months, write 0]**

- 1 Medical problems? _____
- 2 Psychiatric or mental health issues? _____ (e.g. therapist, social worker, psychiatrist)
- 3 Problems (of your own) with drugs? _____
- 4 Problems (of your own) with alcohol? _____
- 5 Significant family problems? _____ (e.g. counselor, family specialist, social worker)

16. During the past 3 months, how many times have you been hospitalized for: **[if no visits in past 3 months, write 0]**

- 1 Medical problems? _____
- 2 Psychiatric or mental health issues? _____
- 3 Problems (of your own) with drugs? _____
- 4 Problems (of your own) with alcohol? _____

Emergency care use/injury

17. During the past 3 months, how many times have you gone to the emergency room for yourself? _____

[if no prior ER visits in past 3 months, write 0]

If patient had no prior emergency room visits in the last 3 months, skip to question 19

18. What were the reason(s) for your prior visit(s)? (*Indicate all that apply*)

- | | | |
|---------------------|----------------------------|--------------|
| _____ Injury | _____ Medical (non-injury) | _____ Ob/Gyn |
| _____ Mental Health | _____ Drug / Alcohol | |

19. How many times in the last 3 months have you had injuries that required medical attention? _____

[if no significant injuries in past 3 months, write 0]

20. In the past 3 months, what is the TOTAL number of DAYS you on which you were unable to do what was normally expected of you (e.g. work, childcare, household management) because of illness or injury? _____

Depression (CES-D10)

Interviewer says: "Now I'm going to ask you questions about how you have been feeling during the last 3 months. Please refer to the card [show card] to describe how often you have had the following problems in the last 3 months."

- CARD READS:
- | | |
|---|--|
| 0 | Rarely or none of the time; less than one a day per week |
| 1 | Some or little of the time; 1-2 days per week |
| 2 | Occasionally or moderate amount of the time; 3-4 days per week |
| 3 | Most or all of the time; 5-7 days per week |

21. _____ I was bothered by things that usually don't bother me.

25. _____ I had trouble keeping my mind on what I was doing.

26. _____ I felt depressed.

27. _____ I felt that everything I did was an effort.

28. _____ I felt hopeful about the future.

29. _____ I felt fearful.

30. _____ My sleep was restless.

31. _____ I was happy.

33. _____ I felt lonely.

39. _____ I could not "get going."

Self-Efficacy (Generalized Scale)

Interviewer says: "Now I have some questions about how you deal with various life events. Please describe how true the following statements are of your experience over the past 3 months, using the following scale." **[SHOW CARD IF POSSIBLE]**

- SCALE:
- | | |
|---|-----------------|
| 1 | Not at all true |
| 2 | A little true |
| 3 | Moderately true |
| 4 | Exactly true |

40. _____ I can always manage to solve difficult problems if I try hard enough.

41. _____ If someone opposes me, I can find the means and ways to get what I want.

42. _____ It is easy for me to stick to my aims and accomplish my goals.

43. _____ I am confident that I could deal efficiently with unexpected events.

44. _____ Thanks to my resourcefulness, I know how to handle unforeseen situations.

45. _____ I can solve most problems if I invest the necessary effort.

46. _____ I can remain calm when facing difficulties because I can rely on my coping abilities.

47. _____ When I am confronted with a problem, I can usually find several solutions.

48. _____ If I am in trouble, I can usually think of a solution.

49. _____ I can usually handle whatever comes my way.

50. _____ I am able to adapt when changes occur.

51. _____ I tend to bounce back after illness, injury or other hardships.

Social Support (Chicago Women's Health Risk Study - SHS)

Interviewer says: "Now I'll be asking you about the supports you have in your life. Please answer yes or no."

52. Do you have someone you can talk to about any problem?

- 0 No
- 1 Yes

53. Do you have someone you could stay with if needed?

- 0 No
- 1 Yes

54. Do you have someone you could borrow money from if needed?

- 0 No
- 1 Yes

Quality of life (WHO)

Interviewer says: "Now I have some questions about how you feel about your life overall."

55. How would you rate your quality of life?

- 1 Very good
- 2 Good
- 3 Neither good nor poor
- 4 Poor
- 5 Very poor

56. How much do you enjoy life?

- 1 Extremely
- 2 Very much
- 3 Moderately
- 4 A little
- 5 Not at all

57. How safe do you feel in your daily life?

- 1 Extremely
- 2 Very much
- 3 Moderately
- 4 A little
- 5 Not at all

Health Behaviors (GENAICS)

Interviewer says: "Now I'll be asking you questions about your health habits in the last 3 months."

58. How many days per week do you engage in vigorous physical exercise (15 minutes duration or more) (e.g., walking briskly, running, bicycling, swimming)? _____

59. In the past 3 months have you been dieting to lose weight?

- 0 No
- 1 Yes

60. In the past 3 months have you used any tobacco products?

- 0 No
- 1 Yes

a. On average, how many cigarettes/cigar/pipe/pinch do you smoke/use each day? **[20 cigarettes/pack]**

- 1 1-9
- 2 10-19
- 3 20-29
- 4 30 or more

61. In the past 3 months, on average, how many hours of sleep have you gotten each night? _____

62. In the last 3 months, how often have you had difficulty getting to sleep?

- 1 Never
- 2 Rarely
- 3 Sometimes
- 4 Often

Heavy Episodic Drinking (AUDIT)

Interviewer says: "Now I am going to ask you some questions about your use of alcohol."

	Questions	0	1	2	3	4
63.	How often do you have a drink containing alcohol?	Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 or more times a week
64.	How many drinks containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
65.	How often do you have four or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
66.	How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
67.	How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
68.	How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
69.	How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
70.	How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
71.	Have you or someone else been injured because of your drinking?	No		Yes, but not in the last year		Yes, during the last year
72.	Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, during the last year
Column Total		0				

Timeline Follow Back (TLFB Script)**Interviewer Directions:**

IF IN PERSON, Provide participant with Timeline Follow Back Calendar. Circle today's date and the date 4 weeks back. The respondent will be answering questions within this one month timeframe. The participant will use this calendar to record the number of drinks consumed each day.

IF ON THE PHONE, Ask participant if they have a calendar they can use as a reference in order to complete the next set of questions. Tell participant the start and end dates and ask them to provide you with the number of drinks consumed each day. You should write their responses on the TLFB as they state them.

Using the following script you will prompt respondents to think about their drinking with respect to national holidays, personal "special" days (i.e. birthdays), and regular drinking patterns (often centered around specific weekly events). Be sure to attach completed TLFB Calendar to the completed interview.

Interviewer script: "Now I'm going to ask you some questions about how much alcohol you've had to drink over the last month (28 days). This includes the time period between:

START DATE: ____/____/____ & **END DATE:** ____/____/____ (yesterday).

"Sometimes if you think about various times of the month or special days that occurred during the past month, it can also help you to recall how much alcohol you've had to drink. Do you have a calendar available that you can use as a reference? For instance, did you take any vacations during the past thirty days?"

Interviewer should now prompt a participant's recall by mentioning the following:

- Vacations
- Weddings/birthdays
- Pay days
- Certain days of the week: every Thursday when playing cards
- Seasonal: around the holidays

Data Entry Directions: After the interview is complete, be sure to attach a completed calendar to the WHI. When we enter data into the database, we will **enter the start date and end date and the number of drinks consumed on day 1 (start date) through day 28 (end date) – so make sure your calendar is legible!**

Intoxication Question (GENACIS)

Interviewer says: "Thank you for spending time earlier answering questions about your drinking. I just have one additional question about your use of alcoholic beverages during the last 3 months." [SHOW CARD IF POSSIBLE]

73. About how often in the last 3 months did you drink enough to feel drunk—that is, where drinking noticeably affected your thinking, talking and behavior?

- 0 Never
- 1 Less than Monthly
- 2 Monthly
- 3 Weekly
- 4 Daily or Almost Daily

Partner's Drinking (GENAICS)

Check here if participant has not had a partner in the past 3 months and Skip to Question 80.

Interviewer says: Now I'm going to ask you some questions about your current or most recent partner's drinking over the past 3 months."

74. In the past 3 months, how often has YOUR PARTNER had a drink containing alcohol?

1 Never

74a. If never: Has your partner ever had a drinking problem? → **IF NEVER, After Q. 74a, skip to question 77.**

0 No

1 Yes, in recovery now

Monthly or less

2 2 to 4 times a month

3 2 to 3 times a week

4 4 or more times a week

75. In the past 3 months, how many drinks does YOUR PARTNER have on a typical day when he/she is drinking?

1 1 or 2

2 3 or 4

3 5 or 6

4 7 to 9

5 10 or more standard drinks

76. In the past 3 months, how often has YOUR PARTNER had (**4** if partner is female, **5** if male) or more drinks on one occasion?

1 Never

2 Less than monthly

3 Monthly

4 Weekly

5 Daily or almost daily

77. During the last 3 months, how much of your drinking has been with your partner?

1 All or almost all occasions

2 Most occasions

3 Some occasions

4 A few occasions

5 Never

78. In the past three months, when you and your partner quarreled, about how often has your partner been drinking?

[SHOW CARD IF POSSIBLE]

1 All of the time

2 Most of the time

3 More often than not

4 Occasionally

5 Rarely

6 Never

7 Partner does not drink

79. In the past three months, when you and your partner quarreled, about how often have you been drinking?
[SHOW CARD IF POSSIBLE]

- 1 All of the time
- 2 Most of the time
- 3 More often than not
- 4 Occasionally
- 5 Rarely
- 6 Never
- 7 I do not drink

Supplementary Drug Use (GENACIS)

Interviewer says: "I'm going to read you a list of questions about your potential involvement with drugs other than alcohol and tobacco during the past 3 months. When I say 'drug abuse' I mean the use of illegal drugs and the inappropriate or misuse of prescribed or over-the-counter medications. These questions refer to the past 3 months."

80. In the past three months, have you used marijuana?

- 0 No
- 1 Yes

80a. If yes, in the past three months how many times have you used marijuana?

- 0 Never
- 1 Less than once a week (1-3 times)
- 2 About once a week (4-5 times)
- 3 More than once a week but not every day
- 4 Daily or almost daily

81. In the past three months, has your current or most recent partner used marijuana?

- 0 No
- 1 Yes
- 2 No partner in past 3 months

82. In the past 3 months, have you used street drugs other than marijuana?

- 0 No
- 1 Yes

82a. If yes, which street drugs have you used in the past 3 months?

Solvents Tranquilizers (e.g. Valium) Barbituates (e.g. downers)
 Cocaine Stimulants (e.g. Speed) Hallucinogens (e.g. LSD)
 Narcotics (e.g. Heroin) Other _____

83. In the past 3 months, have you taken any prescription drugs that were not prescribed for you – or taken the drug in a manner that was not prescribed?

- 0 No
- 1 Yes

83a. If yes, which drugs? _____

84. In the past 3 months, has your current or most recent partner used street drugs (not including marijuana) or prescription drugs?

- 0 No
- 1 Yes

Relationship Satisfaction (Dyadic Adjustment Scale)

Interviewer says: "Now I'm going to ask you about your intimate relationships. That is, a sexual or romantic relationship with a boy/girlfriend, spouse, partner, lover, etc. I'd like you to answer these questions based on a relationship that you are in currently, or, if you are not currently in a relationship, about the person with whom you were most recently in a relationship."

85. The following numbers represent different degrees of happiness in your relationship. The middle point, "happy," represents the degree of happiness of most relationships. Please circle the number which best describes the degree of happiness, all things considered, in your relationship. **[SHOW CARD IF POSSIBLE]**

0	1	2	3	4	5	6
Extremely Unhappy	Fairly Unhappy	A Little Unhappy	Happy	Very Happy	Extremely Happy	Perfectly Happy

IPV Severity (CTS2S)

Check here if participant has not had a partner in the past 3 months and Skip to Question 102.

Interviewer says: The next few questions will ask about your relationship. They are a series of related questions and therefore, some questions may seem repetitive."

"For the questions below, using the following scale, please tell me how many times in the past 3 MONTHS each of you did these things." **[SHOW CARD IF POSSIBLE]**

- | | |
|---|---|
| 0 = This has never happened | 4 = 6 - 10 times in the past 3 MONTHS |
| 1 = Once in the past 3 MONTHS | 5 = 11 - 20 times in the past 3 MONTHS |
| 2 = Twice in the past 3 MONTHS | 6 = More than 20 times in the past 3 MONTHS |
| 3 = 3 - 5 times in the past 3 MONTHS | P = Did NOT happen in the past 3 MONTHS, but it did happen before. |

86. I insulted or swore or shouted or yelled at my partner.	0	1	2	3	4	5	6	P
87. My partner insulted or swore or shouted or yelled at me.	0	1	2	3	4	5	6	P
88. I had a sprain, bruise, or small cut, or felt pain the next day because of a fight with my partner.	0	1	2	3	4	5	6	P
89. My partner had a sprain, bruise, or small cut, or felt pain the next day because of a fight with me.	0	1	2	3	4	5	6	P
90. I pushed, shoved, or slapped my partner.	0	1	2	3	4	5	6	P
91. My partner pushed, shoved, or slapped me.	0	1	2	3	4	5	6	P
92. I punched, kicked, or beat-up my partner.	0	1	2	3	4	5	6	P
93. My partner punched, kicked, or beat-me-up.	0	1	2	3	4	5	6	P
94. I destroyed something belonging to my partner or threatened to hit my partner.	0	1	2	3	4	5	6	P
95. My partner destroyed something belonging to me or threatened to hit me.	0	1	2	3	4	5	6	P
96. I went to see a doctor or needed to see a doctor because of a fight with my partner.	0	1	2	3	4	5	6	P
97. My partner went to see a doctor or needed to see a doctor because of a fight with me.	0	1	2	3	4	5	6	P
98. I used force (like hitting, holding down, or using a weapon) to make my partner have sex.	0	1	2	3	4	5	6	P

99.	My partner used force (like hitting, holding down, or using a weapon) to make me have sex.	0	1	2	3	4	5	6	P
100.	I insisted on sex when my partner did not want to or insisted on sex without a condom (but did not use physical force).	0	1	2	3	4	5	6	P
101.	My partner insisted on sex when I did not want to or insisted on sex without a condom (but did not use physical force).	0	1	2	3	4	5	6	P

IPV Severity (CAS Assessment)

Interview says: "We would like to know if you have had any of the experiences listed below with your previous and/or current partner. Please tell me how many times in the PAST 3 MONTHS that you experienced these actions using the following scale:"
[SHOW CARD IF POSSIBLE]

SCALE:

0	1	2	3	4	5
Never	Only Once	Several Times	Once/ Month	Once/ Week	Daily

Actions	How often it happened						
	Never	Only Once	Several Times	Once/ Month	Once/ Week	Daily	
102.	Told me that I wasn't good enough	0	1	2	3	4	5
103.	Kept me from medical care	0	1	2	3	4	5
104.	Followed me	0	1	2	3	4	5
105.	Tried to turn my family, friends and children against me	0	1	2	3	4	5
106.	Locked me in the bedroom	0	1	2	3	4	5
107.	Slapped me	0	1	2	3	4	5
108.	Forced me to have sex	0	1	2	3	4	5
109.	Told me that I was ugly	0	1	2	3	4	5
110.	Tried to keep me from seeing or talking to my family	0	1	2	3	4	5
111.	Threw me	0	1	2	3	4	5
112.	Hung around outside my house	0	1	2	3	4	5
113.	Blamed me for causing their violent behavior	0	1	2	3	4	5
114.	Harassed me over the telephone	0	1	2	3	4	5
115.	Shook me	0	1	2	3	4	5
116.	Tried to force me to have sex	0	1	2	3	4	5
117.	Harassed me at work	0	1	2	3	4	5
118.	Pushed, grabbed or shoved me	0	1	2	3	4	5
119.	Used a knife or gun or other weapon	0	1	2	3	4	5
120.	Became upset if dinner/housework wasn't done	0	1	2	3	4	5
121.	Told me that I was crazy	0	1	2	3	4	5
122.	Told me that no one would ever want me	0	1	2	3	4	5
123.	Took my wallet and left me stranded	0	1	2	3	4	5
124.	Hit or tried to hit me with something	0	1	2	3	4	5
125.	Did not want me to socialize with my female friends	0	1	2	3	4	5
126.	Put foreign objects in my vagina	0	1	2	3	4	5
127.	Refused to let me work outside the home	0	1	2	3	4	5
128.	Kicked me, bit me or hit me with a fist	0	1	2	3	4	5
129.	Tried to convince my friends, family or children that I was crazy	0	1	2	3	4	5
130.	Told me that I was stupid	0	1	2	3	4	5
131.	Beat me up	0	1	2	3	4	5

IPV Severity (WEB Assessment)

Check here if participant has not had any partner in the past 3 months and Skip to Question 162.

Directions: Please remember to adjust the nouns/pronouns depending on the gender of the partner.

Interviewer says: "The following are a number of statements that women have used to describe their lives with their partners. Please tell me how much you agree or disagree with each statement, using the following scale."

[SHOW CARD IF POSSIBLE]

SCALE:

1	2	3	4	5	6
Disagree	Disagree	Disagree	Agree	Agree	Agree
Strongly	Somewhat	A Little	A Little	Somewhat	Strongly

132.	He makes me feel unsafe even in my own home.	1	2	3	4	5	6
133.	I feel ashamed of the things he does to me.	1	2	3	4	5	6
134.	I try not to rock the boat because I am afraid of what he might do.	1	2	3	4	5	6
135.	I feel like I am programmed to react a certain way to him.	1	2	3	4	5	6
136.	I feel like he keeps me prisoner.	1	2	3	4	5	6
137.	He makes me feel like I have no control over my life, no power, no protection.	1	2	3	4	5	6
138.	I hide the truth from others because I am afraid not to.	1	2	3	4	5	6
139.	I feel owned and controlled by him.	1	2	3	4	5	6
140.	He can scare me without laying a hand on me.	1	2	3	4	5	6
141.	He has a look that goes straight through me and terrifies me.	1	2	3	4	5	6

IPV Severity (Danger Assessment)

Directions: Please remember to adjust the nouns/pronouns depending on the gender of the partner.

Interviewer says: "For the following questions, please answer YES or NO"

	YES	NO
142. Has the physical violence increased in severity or frequency over the past year?	1	0
143. Does he own a gun?	1	0
144. Have you left him after living together during the past year? (if you have never lived with him, check here ____)	1	0
145. Is he unemployed?	1	0
146. Has he ever used a weapon against you or threatened you with a lethal weapon? (if yes, was the weapon a gun?____)	1	0
147. Does he threaten to kill you?	1	0
148. Has he avoided being arrested for domestic violence?	1	0
149. Do you have a child that is not his?	1	0
150. Has he ever forced you to have sex when you did not wish to do so?	1	0
151. Does he ever try to choke you?	1	0

152. Does he use illegal drugs? (By drugs, I mean “uppers” or amphetamines, speed, angel dust, cocaine, “crack”, street drugs or mixtures; not marijuana) 1 0
153. Is he an alcoholic or problem drinker? 1 0
154. Does he control most or all of your daily activities? (For instance: does he tell you who you can be friends with, when you can see your family, how much money you can use, or when you can take the car?) 1 0
(if he tries, but you do not let him, check here:____)
155. Is he violently and constantly jealous of you? 1 0
156. Have you ever been beaten by him while you were pregnant? 1 0
(if you have never been pregnant with him, check here:____)
157. Has he ever threatened or tried to commit suicide? 1 0
158. Does he threaten to harm your children? 1 0
159. Do you believe he is capable of killing you? 1 0
160. Does he follow or spy on you, leave threatening notes or voicemail messages, destroy your property, or call you when you don't want him to? 1 0
161. Have you ever threatened or tried to commit suicide? 1 0
(if yes, are you currently feeling that way? ____)
*If current **Suicidal Ideation**, once interview is concluded, notify Dr. Karin Rhodes and/or offer than the option to come in for the study intervention. Follow-up is important with this participant.*

PTSD (Primary Care PTSD Screen)

Interviewer says: “Have you ever had any experience in your life that was so frightening, horrible, or upsetting that, in the past 3 months, you:”

162.	Have had nightmares about it or thought about it when you did not want to?	1 Yes	0 No
163.	Tried hard not to think about it or went out of your way to avoid situations that reminded you of it?	1 Yes	0 No
164.	Were constantly on guard, watchful, or easily startled?	1 Yes	0 No
165.	Felt numb or detached from others, activities, or your surroundings?	1 Yes	0 No

Sexual Abuse History (GENACIS)

166. When you were growing up, did someone try to make you do sexual things or watch sexual things? This could be by a family member or someone other than a family member.
0 No
1 Yes
166a. **If Yes**, did this happen before you were 16 years old (age 15 or younger)?
0 No
1 Yes
167. Did you feel that you were sexually abused when you were growing up? This could be by a family member or someone other than a family member.
0 No
1 Yes

Arrest History

168. In the last 3 months, has your partner been arrested for anything?

- 0 No
- 1 Yes (If yes, on what charges? _____)
- 2 No partner in the past 3 months

169. In the last 3 months, have you been arrested for anything?

- 0 No
- 1 Yes (If yes, on what charges? _____)

Engagement with agencies/support

Interviewer says: "Now I have some questions about you and your partner's use of supportive services."

170. In the last 3 months, have YOU used any police or court services because of family violence? (Such as calling the police, meeting with a detective or prosecutor, going to family court, for divorce or custody, or applying for an order of protection?)

- 0 No
- 1 Yes (If yes, describe: _____)

171. In the last 3 months, have YOU used any domestic violence services, including shelter, legal services, counseling, or support group services?

- 0 No
- 1 Yes (If yes, describe: _____)

172. In the last 3 months, have YOU used any supportive services for alcohol use (e.g. counseling, detox, AA)?

- 0 No
- 1 Yes (If yes, describe: _____)

173. In the last 3 months, has your PARTNER used any supportive services for alcohol use (e.g. counseling, detox, AA)?

- 0 No
- 1 Yes (If yes, describe: _____)
- 2 No partner in the past 3 months

Motivation to Change (Importance / Confidence Rulers)

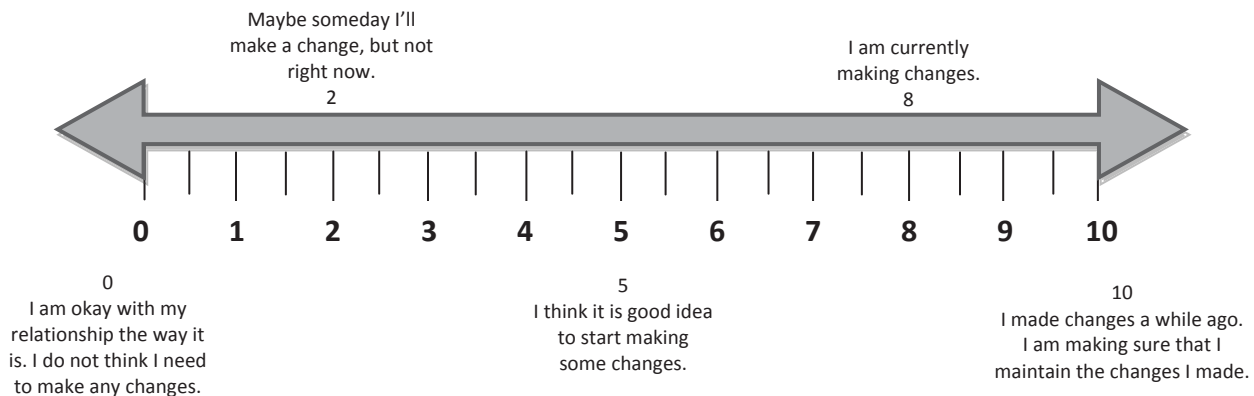
Interviewer says: "Please refer to importance and confidence scales [show card]. These questions refer to your romantic relationships in general." **[Show Card if Possible]**

Importance Ruler									
Not important					Very important				
1	2	3	4	5	6	7	8	9	10

Confidence Ruler									
Not confident					Very confident				
1	2	3	4	5	6	7	8	9	10

- 174. On a scale of 1-10, where 1 means "not at all important" and 10 means "very important," how important is it to you to take steps to change the level of conflict in your romantic relationships? _____
- 175. On a scale of 1-10, where 1 means "not at all confident" and 10 means "very confident," how confident are you - if you made a decision to change – that you could change the level of conflict in your romantic relationships? _____
- 176. On a scale of 1-10, where 1 means "not at all important" and 10 means "very important," how important is it to you to take steps to reduce your alcohol use? _____
- 177. On a scale of 1-10, where 1 means "not at all confident" and 10 means "very confident," how confident are you - if you made a decision to change – that you could reduce your alcohol use? _____

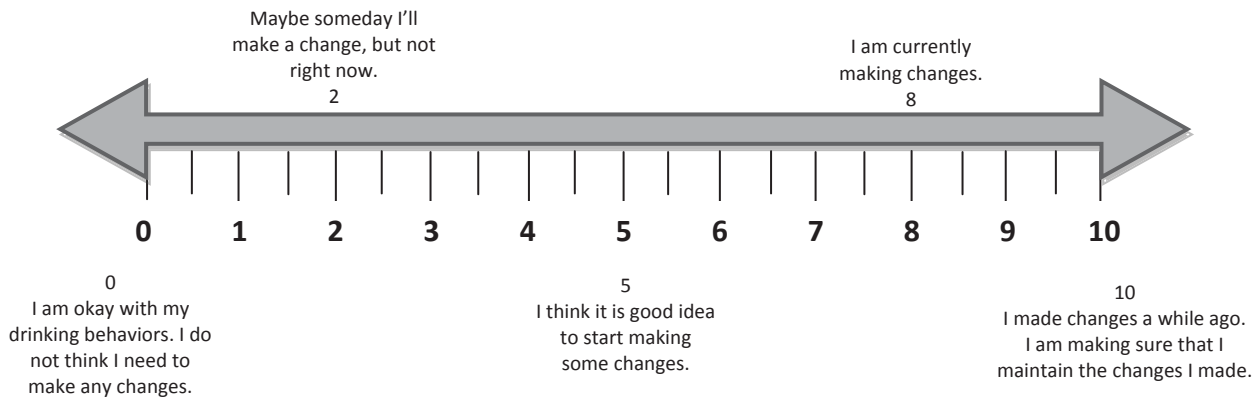
Readiness to Change - Relationship



Interviewer says: "Using this ruler, we would like you to choose a number between 0 and 10 to indicate how ready you are to make a change in your relationship with your [INDEX] partner. You can choose 0, "I am okay with my relationship the way it is. I do not think I need to make any changes" or 10, "I made changes a while ago. I am making sure that I maintain the changes I made" or any number in between. A score of 2 indicates: "maybe someday I'll make a change, but not right now", 5 indicates: "I think it is a good idea to start making changes", and 8 indicates: "I am currently making changes".

- 178. Please pick a number between 0 and 10 to indicate how ready you are to make changes in your relationship. _____

Readiness to Change – Drinking Behaviors



Interviewer says: “Using this ruler, we would like you to choose a number between 0 and 10 to indicate how ready you are to make a change in your drinking behaviors. You can choose 0, “I am okay with my drinking behaviors. I do not think I need to make any changes” or 10, “I made changes a while ago. I am making sure that I maintain the changes I made” or any number in between. A score of 2 indicates: “maybe someday I’ll make a change, but not right now”, 5 indicates: “I think it is a good idea to start making changes”, and 8 indicates: “I am currently making changes”.

179. Please pick a number between 0 and 10 to indicate how ready you are to make a change in your drinking behaviors. _____

Steps to Safety

180. Have you taken any steps in the past 3 months to increase your safety?

0 No

1 Yes

180a. What were they? (describe)

Satisfaction with Study

181. How satisfied are you with your participation in this study? **[SHOW CARD IF POSSIBLE]**

1 Extremely

2 Very

3 Somewhat

4 Not Very

5 Not at All

182. What impact, if any, has being in this study had on your level of safety? On a Scale of 1-5 from Safer to Less Safe, do you feel **[SHOW CARD IF POSSIBLE]**...

1 Safer 2 3 About the same 4 5 Less Safe

183. What impact, if any, has being in this study had your drinking? On a Scale of 1-5 from Less to More, are you drinking **[SHOW CARD IF POSSIBLE]**...

1 Less 2 3 About the same 4 5 More

INTERVIEWER DIRECTIONS: THANK THE SUBJECT FOR THEIR PARTICIPATION IN THE STUDY. BE SURE TO OFFER THE BRIEF HEALTH PROMOTION SESSION AT THIS TIME. THE SESSION CAN OCCUR IN PERSON AT THE ED OR OVER THE PHONE. PLEASE COMPLETE THE FOLLOWING:

⇒ Is the participant interested in receiving the intervention? YES NO

⇒ If No, please prompt for reason why not interested: _____

⇒ If Yes, preferred method: Phone In-Person

Inform MET Therapist, and tell participant: Someone will follow up with then in the next few days.

⇒ Referrals Given YES NO (REASON) _____

Study ID#: _____

Date: _____

TIMELINE FOLLOWBACK CALENDAR: 2011

1 Standard Drink is Equal to



**One 12 oz
can/bottle of
beer**



**One 5 oz glass of
regular (12%)
wine**



**1 ½ oz of hard liquor
(e.g. rum, vodka,
whiskey)**



**1 mixed or straight
drink with 1 ½ oz
hard liquor**

Complete the Following

Start Date (Day 1): _____ **End Date (yesterday):** _____

MO DY YR MO DY YR

	SUN	MON	TUES	WED	THURS	FRI	SAT
			1	2	3	4	5
F	6	7	8	9 <small>Ash Wednesday</small>	10	11	12
E	13	14 <small>Valentine's Day</small>	15	16	17	18	19
B	20	21 <small>Presidents' Day</small>	22	23	24	25	26
	27	28	1	2	3	4	5
M	6	7	8	9	10	11	12
A	13	14	15	16	17 <small>St. Patrick's Day</small>	18	19
R	20	21	22	23	24	25	26
	27	28	29	30	31	1	2
A	3	4	5	6	7	8	9
P	10	11	12	13	14	15	16
R	17	18	19 <small>Passover</small>	20	21	22 <small>Good Friday</small>	23
	24 <small>Easter</small>	25	26	27	28	29	30
2011	1	2	3	4	5	6	7
M	8 <small>Mother's Day</small>	9	10	11	12	13	14
A	15	16	17	18	19	20	21
Y	22	23	24	25	26	27	28
	29	30 <small>Memorial Day</small>	31	1	2	3	4

	SUN	MON	TUES	WED	THURS	FRI	SAT
				1	2	3	4
J	5	6	7	8	9	10	11
U	12	13	14	15	16	17	18
N	19 ^{Father's Day}	20	21	22	23	24	25
	26	27	28	29	30	1	2
J	3	4 ^{Independence Day}	5	6	7	8	9
U	10	11	12	13	14	15	16
L	17	18	19	20	21	22	23
	24	25	26	27	28	29	30
	31	1	2	3	4	5	6
A	7	8	9	10	11	12	13
U	14	15	16	17	18	19	20
G	21	22	23	24	25	26	27
	28	29	30	31	1	2	3
S	4	5 ^{Labor Day}	6	7	8	9	10
E	11	12	13	14	15	16	17
P	18	19	20	21	22	23	24
	25	26	27	28	29	30	1
O	2	3	4 ^{Rosh Hashanah}	5	6	7	8
C	9	10 ^{Columbus Day}	11	12	13 ^{Yom Kippur}	14	15
T	16	17	18	19	20	21	22
	23	24	25	26	27	28	29
	30	31 ^{Halloween}	1	2	3	4	5
N	6	7	8	9	10	11 ^{Veterans' Day}	12
O	13	14	15	16	17	18	19
V	20	21	22	23	24 ^{Thanksgiving}	25	26
	27	28	29	30			

SCRIPT FOR INTERACTIVE VOICE RESPONSE SYSTEM

Participants will be asked to call the interactive voice response (IVR) telephone system once per week over a 12 week period. The script below is the recorded script that will be heard by callers. Callers will be prompted to respond by pressing numbers on the telephone keypad.

Introduction: *Thank you for calling the patient response line at the Hospital of the University of Pennsylvania. Please enter your Patient number.*

If no patient ID is entered, prompt for code: *Please enter your patient number.*

If patient ID entered incorrectly, prompt for code: *The patient number you entered was not recognized .Please re-enter your Patient number.*

If patient number entered incorrectly a second time, prompt for code again: *The patient number you entered was not recognized. Please re-enter your Patient number.*

If patient number entered incorrectly a third time: *The number you entered was not recognized. If you cannot remember your number, please call us at 215-XXX-XXXX and we will remind you. Again the telephone number is 215-XXX-XXXX. Thank you for calling. Good bye.*

If identifiable patient ID is entered: *Thanks very much for calling. Please enter you Patient Password.*

If no code is entered, prompt for code: *Please enter your password.*

If code entered incorrectly, prompt for code: *The password you entered was not recognized .Please re-enter your Patient Password.*

If code entered incorrectly a second time, prompt for code again: *The password you entered was not recognized. Please re-enter your Patient Password.*

If code entered incorrectly a third time: *The password you entered was not recognized. If you cannot remember your password, please call us at 215-XXX-XXXX and we will remind you. Again the telephone number is 215-XXX-XXXX. Thank you for calling. Good bye.*

If code entered correctly: *Thanks very much for calling. This survey is run by the team you spoke with in the Emergency Department. If you are in danger or need medical assistance, hang up and call 9-1-1 right now. If you are worried about someone confronting you while you are on the phone, you can hang up and call back at a better time.*

If it is patients first or second time calling: *We are conducting this survey to study how often people experience abuse or violence in their relationship, and to ask about your consumption of alcoholic beverages. All responses will be kept strictly confidential and used anonymously for research reasons; your name will not be connected to any of the things that you report to us. Please respond by pressing numbers on the telephone keypad. If you are unsure of the answer to a question, please select the answer that fits best.*

We are asking you to call this survey once per week for 12 weeks. For each completed call, \$10 will be added to the debit card you were given, as a way to thank you. After each call, please wait one full week before calling again – the system will not let you take the survey more often than that.

If this is not the callers first or second call she jumps to here: *This is your (first, second, ...) week of the 12 week survey. So far you have made [#] calls and have been given [\$ Amount] on your card.*

Is it ok to ask you some questions now?

Press 1 for YES.

Press 2 for NO. Please call the number for the telephone survey again anytime if you would like to do so. Thank you for your time. Goodbye.

If Yes: Thank you. You will be asked a total of 16 questions that all refer to your experiences IN THE LAST WEEK:

The first 9 questions are about conflict in your relationship. When you were seen in the Emergency Department, we asked you questions about your partner, who was your current or former spouse or partner. In the following questions, when we ask about your partner, please refer to this person.

These questions ask about how frequently certain events happened in the past week. Please respond by pressing a number from 0 to 8 to indicate how many times this happened. 0 means that it did not happen in the past week; 8 means that it happened 8 times OR MORE in the past week.

1. How many times in the past week did you see your partner? Press a number from 0 to 8 for the number of times you have seen your partner; If you press "8" it means 8 OR MORE.

NOTE: If the subject presses "0" : You have pressed 0 which means that you have not had ANY contact with your partner (have not seen or heard from him/her in the last week)
If this is correct, press 1. If you have had contact in the last week, press 2.(If "1" they will be skipped to the alcohol questions beginning with question 10.)

2. In the past week, how many times has your partner insulted, swore, shouted, or yelled at you? Press a number from 0 to 8.

3. In the past week, how many times have you had a sprain, bruise, or small cut, or felt pain the next day because of a fight with your partner? Press a number from 0 to 8.

4. In the past week, how many times has your partner pushed, shoved, or slapped you? Press a number from 0 to 8.

5. In the past week, how many times has your partner punched, kicked, or beat-you-up? Press a number from 0 to 8.

6. In the past week, how many times has your partner destroyed something belonging to you or threatened to hit you? Press a number from 0 to 8.

7. In the past week, how many times have you gone to see a doctor, or needed to see a doctor, because of a fight with your partner? Press a number from 0 to 8.

8. In the past week, how many times has your partner used force (like hitting, holding down, or using a weapon) to make you have sex? Press a number from 0 to 8.

9. In the past week, how many times has your partner insisted on having sex when you did not want to, or insisted on sex without a condom (but did not use physical force)? Press a number from 0 to 8.

The next 3 questions are about your use of alcoholic beverages over the last week.

10. In the past week, on how many days have you had a drink containing alcohol? Press the number (between 0 and 7) of days that you have had a drink containing alcohol in the past week.

You have pressed 0 which means that you have not had ANY alcohol this week. Press 1 if this is correct, press 2 if you had any alcohol. Note: if the person presses "0" skip questions 11 & 12.

11. In the past week, how many drinks have you had on a typical day when you are drinking. Press the number (between 1 and 9) of drinks you have had on a typical day when you are drinking. (9 means you have had 9 OR MORE drinks)

12. In the past week, how often have you had four or more drinks in one day? Press the number (between 0 and 7) for the number of days in the past week when you have had four or more drinks

If patient reaches this point in the survey, this IVR call should be coded as complete and the participant will be provided with 10 on their card and will be locked from the system for 6 days.

The last 4 questions are about your use of health or community support services IN THE LAST WEEK. Please note that this call does not count as a service. For each question, press 1 for yes or 2 for no.

13. In the past week, have you used any emergency department services?

14. In the past week, have you sought help for domestic violence from either family or friends or a domestic violence agency?

15. In the past week, have you sought help for domestic violence from the police or courts?

16. In the past week, have you sought help for drinking from either a primary care doctor, a support group, or a substance abuse treatment facility?

Closing Scripts
(Based on timeframe and other call circumstances)

AT THE END OF THE SURVEY (during weeks 1 through 11): *Thank you for your time and your honesty. \$10 will now be added electronically to your debit card as a way to thank you. Please allow a day or two for this transaction to go through. Please call again in one week to respond to our survey again. If you have lost your debit card, please call us at 215-XXX-XXXX and we will arrange to give you a new card. We want to let you know there is a toll-free hotline for people who are in an abusive relationship can call for help. The telephone number is 1-866-SAFE-14. That is 1-866-723-3014; you can call this number anytime. Thank you very much again for helping us with this study. Good bye.*

AT THE END OF THE 12 WEEK IVR SURVEY: *This is your last phone survey. Thank you for your time and your honesty. \$10 will now be electronically added to your debit card as a way to thank you. Including this call, you completed [X] phone calls during the past several weeks. A bonus of \$5 dollars per call will also be added to your debit card. Please allow a day or two for this transaction to go through. As a reminder, the study also includes interviews at 3, 6, and 12 months after your initial enrollment, so we will be calling you soon using the contact plan and phone number you gave us before. If your contact information has changed, please call 215-573-3055 to let us know. Thank you very much again for helping us with this study; your participation will help us understand the experiences and needs of women who are in similar situations. We want to let you know there is a toll-free hotline for people who are in an abusive relationship can call for help. The telephone number is 1-866-SAFE-14. That is 1-866-723-3014; you can call this number anytime. Thank you very much again for helping us with this study. Good bye.*

If questions 1 through 12 are answered incorrectly three times in a row (“This is not a valid key”) the participant will hear a goodbye script: *It appears you are having difficulties answering the survey questions this time. Please hang up and call use back at a time that is more convenient for you. If you continue to experience problems with the survey and need assistance please call us at 215-573-3055. Thank you for calling Good bye.*

IF THE PARTICIPANT CALLS BACK WHEN THEY ARE BLOCKED FROM THE SYSTEM (During 6 day period after last completed survey): *Thanks very much for calling. You have reached the telephone survey being run by the team you spoke with in the Emergency Department. If you are in danger or need medical assistance, hang up and call 9-1-1 right now. You have already completed the survey for this week and are unable to complete survey at this time. After each completed survey, you must wait one week before calling again. Please call back on or any day after [date next able to call – determined by adding 6 days to last call date].*

We want to let you know there is a toll-free hotline for people who are in abusive relationships can call for help. The telephone number is 1-866-SAFE-14. That is 1-866-723-3014; you can call this number any time. Thank you very much for helping use with this study. Good bye.

IF THE PARTICIPANT CALLS BACK AFTER THEY ARE BLOCKED FROM THE IVRS SURVEY (Set at 13 weeks from the patient enrollment date): *Thanks very much for calling. You have reached the telephone survey being run by the team you spoke with in the Emergency Department. If you are in danger or need medical assistance, hang up and call 9-1-1 right now. You have completed the survey portion of the study. As a reminder, the study also includes interviews at 3, 6, and 12 months after your initial enrollment, so we will be calling you soon using the contact plan and phone number you have given us. If your contact information has changed, please call 215-573-3055 to let us know. We want to let you know there is a toll-free hotline for people who are in abusive relationships can call for help. The telephone number is 1-866-SAFE-14. That is 1-866-723-3014; you can call this number any time. Thank you very much for helping us with this study. Good bye.*

Women's Health Study: MET Initial & Booster Session Form

Study ID: _____

Name of MET Therapist: _____

Initial MET Session Info

Date: __/__/____

Location ED Phone

Recorded? Yes No

Length of Conversation (min/sec): _____

MET Booster Session Info

Was a booster session conducted (30 day timeframe)? Yes No

Date: __/__/____

Location ED Phone

Recorded? Yes No

Length of Conversation (min/sec): _____

Booster Script "Hello, this is _____ from the Social Healthy Study. May I speak with _____?"
"Hi, _____. We met on (date). Is this a safe time to talk?"

Therapists: Please check each topic and sub-questions covered during the booster session. More is not necessarily better.

Intimate Partner Violence

- (A) Since your medical visit, tell me what your relationship has been like? (Make notes indicating the nature of any conflict- was it physical? Emotional? Did it result in the need for medical care?)
- (B) We had discussed some things you can do to maintain safety in your relationship when you feel like you might be at risk for harm or harming someone else. What strategies have you tried? How have they worked? What other strategies have you tried?
- (C) Do you feel the need to make any changes in the safety plan you established?
- (D) What is your next step in terms of your plan to _____?
- (E) Given everything we've been discussing, if you could choose the best outcome for your relationship with your partner/ex-partner, what would it be? (Stay together/fix the conflict, Leave, Other_____)
- (F) Please think about the way you are feeling right now. On a scale of 1-10, where 10 means 'very ready' and 1 means 'not at all ready,' how ready do you feel to take steps to make the changes in your relationship that we've been talking about?
- (G) Using a scale where 10 means 'very confident' and 1 means 'not at all confident,' how confident do you feel about your ability to make changes in your relationship?

MET Provider Notes (NOTE: Do Not Use Participant's Name or other Identifiers)

Alcohol Use

- (A) I'm wondering what your alcohol use has been like over the past week or so.
- (B) We discussed some things you can do to engage in safer drinking habits. What strategies have you tried? How have those strategies worked out for you? What other strategies have you tried?
- (C) Do you feel the need to make any changes in the plan you established?
- (D) What is your next step in terms of your plan to change your alcohol use?
- (E) Using the same scale, where 10 means 'very ready' and 1 means 'not at all ready,' how ready do you feel to take steps to make the changes in your life that we've been talking about related to your drinking?
- (F) Using the same scale, where 10 means 'very confident' and 1 means 'not at all confident,' how confident do you feel about your ability to make changes in your drinking?

MET Provider Notes (NOTE: Do Not Use Participant's Name or other Identifiers)

3-25-2011

Goals

- (A) What has it been like for you trying to work on your goal/s?
- (B) Have particular things been challenging for you?
- (C) How have you dealt with them/how do you plan to deal with them?
- (D) What has kept you motivated to keep working toward your goal?

MET Provider Notes (NOTE: Do Not Use Participant's Name or other Identifiers)

Resources/ Referrals

- (A) Do you still have the list of referrals I gave you?
- (B) Have you connected with or tried to connect with any referrals we discussed?
- (C) Are there any/any additional supports that you plan to connect with in the near future?

MET Provider Notes (NOTE: Do Not Use Participant's Name or other Identifiers)

Conclusion/ Evaluation

"As we discussed when we first met, this phone call will conclude the contact that you and I will have. Before you go, I wanted to know if you have any feedback for me about what this experience has been like for you."

- (A) What has been particularly helpful to you?
- (B) What could I have done differently?
- (C) Did any problems come up during your medical visit or afterwards that are related to your participation in this study?
- (D) Finally, is there any additional information that you would like from me or do you have questions for me?

MET Provider Notes (NOTE: Do Not Use Participant's Name or other Identifiers)

Follow-up / Safe-Contact: *"Before we conclude our conversation, I would like to make sure that we have accurate contact information for you. Remember, in addition to you continuing to call in once/week for 12 weeks, a member of our staff will need to contact you by phone at 3, 6, and 12 months for follow up women's health interviews. Your time for these interviews will be reimbursed on your bank card. (Refer to safe contact form to verify patient's current safe contact information is correct.) When they call is it still OK for them to say they are calling from the "Women's Social Health Information Project" ? We really appreciate your participation in the Women's Social Health Information Project and think your input can make a difference."*

_____ **MET Provider checks here once Safe Contact Form is verified.**

Use the space below to record any other qualitative information/ notes below. Do Not Use Participant's Name or other Identifiers
