Baylor College of Medicine

&

CDC

IRB Approvals

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-25409
Status: Approved
Initial Submit Date: 7/18/2009
Approval Period: 10/13/2009 - 10/12/2010

Section Aa: Title & PI

A1. Protocol Title

CONTROLLED EVALUATION OF EXPECT RESPECT SUPPORT GROUPS

A2. Principal Investigator

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A3. Administrative Contact

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A3a. Financial Conflict of Interest

Does the investigator have a financial interest in any non-Baylor sponsor or funding source for this research?

No

A3b. Cooperative Agreement

Is this a cooperative agreement protocol?

No

Which institution is the IRB of record?

BCM: Baylor College of Medicine

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Other: Centers for Disease Control and Prevention

A6a. Institutions where work will be performed:

CDC: Centers for Disease Control - Georgia

A6b. Research will be conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

Section B: Review Path Determination

B1. Full Board or Expedited Review

Is this an compassionate/emergency use situation?
No

If this is a drug study, is an investigational new drug (IND) application required?
N/A

If this is a device study, is an investigational device exemption (IDE) application required?
N/A

If the research involves ONLY blood collection, are subjects healthy, non-pregnant adults

N/A

If the research involves ONLY blood collection for other adults and children, considering age, weight and health of subjects, is the amount drawn in an 8 week period less than 50ml or 3 ml per kg, and with collection not occurring more frequently than 2 times per week?

N/A

Does the research involve ONLY the collection of biological specimens for research purposes by noninvasive means? (e.g. Hair; extracted teeth; excreta, sputum and external secretions; placenta removed at delivery; mucosal and skin cells collected by scraping or swab)

N/A

Does the research involve ONLY the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves? (e.g. EKG, ECHO, EEG, Ultrasound, MRI)

N/A

Does the research involve ONLY materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)?

N/A

Does the research involve ONLY the collection of data from voice, video, digital, or image recordings made for research purposes?

N/A

Does the research involve ONLY individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies?

Yes

Does the research involve pedigree studies, collection and/or storage of specimens for DNA analysis or gene transfer?

No

B2. Exempt From IRB Review

Not Applicable

B3. Waiver of Subject Authorization

Not Applicable

Section C: Background

The prevalence and consequences of teen dating violence make it a public health concern (Wolitzky-Taylor et al., 2008; Eaton, Davis, Barrios, Brener, & Noonan, 2007) that requires early and effective prevention. Despite recent legislation in Texas and Rhode Island that requires schools to provide teen dating violence education, to date, only three prevention strategies—Safe Dates, the Youth Relationships Project, and 4th R (Foshee et al., 1998; Wolfe et al., 2003; Wolfe et al., in press) - have demonstrated reductions in dating violence behaviors in rigorous, controlled evaluations (Hickman, Jaycox, & Aronoff, 2004). In order to protect young people and build an evidence-base of effective prevention strategies, evaluation of additional programs is needed, including those programs currently in the field (Teten, Ball, Valle, Noonan, & Rosenbluth, 2009).

Teens are at risk for experiencing dating abuse beginning with the initiation of dating relationships during early adolescence. Nearly half of 11– to 14-year olds report that they have been in a dating relationship (Teen Research Unlimited, 2008). Among those who experience dating violence victimization, 29% report their first experience of abuse occurred at age 12-13, 40% at age 14-15, and 29% at age 16-17 (Burcky, Reuterman, & Kopsky, 1988). Up to 45% of high school students report experiencing some form of emotional, physical, or sexual violence in their dating relationships (Foshee, 1996; O'Keefe, 1997; Silverman, Rai, Mucci, & Hathaway, 2001). Dating violence is associated with subsequent adverse consequences, including substance abuse, sexual risk behaviors, unintended pregnancy, sexually transmitted diseases, unhealthy weight control behaviors, depression, and suicidality (Teten et al., 2009).

Although traditional conceptualizations of dating violence suggested males were perpetrators and females were victims, surveys of teen dating violence that assess both girls' and boys' violence perpetration consistently report a higher percentage of girls than boys perpetrate physical violence (Foshee, 1996; O'Keefe, 1997; Hickman et al., 2004; Sears, Byers, & Price, 2006). Critics of these findings suggest the effects of male and female-perpetrated physically violent acts differ substantially in terms of injury sustained and fear evoked (Dobash, Dobash, Wilson, & Daly, 1992). Molidor, Tolman, and Kober (2000) found that 48% of girls in their sample and only 4% of boys reported that a violent incident "hurt a lot." Boys more often (54%) responded that they "laughed" about the violence compared to girls (10%). While the context, meaning, and effect of violent behaviors may differ between boys and girls, studies nevertheless point to the importance of supporting both boys and girls in learning skills for healthy relationships. As noted by O'Keefe (1997): "every violent action creates a risk for a violent response or future violent acts" (p. 6). Given the prevalence and age of initiation reported for teen dating and teen dating violence, prevention programs need to involve boys and girls beginning with the middle school years.

Multiple studies suggest that teens' experiences with violence and violence-supportive or accepting attitudes are linked with the perpetration of dating violence (Wolfe, Wekerle, Reitzel-Jaffe, & Lefebvre, 1998; Wolfe, Wekerle, Scott, & Pittman, 2001; Wolfe, Wekerle, Scott, Straatman, & Grasley, 2004; Malik, Sorenson, & Anehensel, 1997; O'Keefe, 1997, 1998). While the mechanism of these associations is unclear, a history of child maltreatment has been associated with boys threatening or carrying out dating violence, with boys experiencing dating violence, and with girls being victims of such violence (Wolfe, Wekerle, Scott, & Pittman, 2001). Witnessing parental violence (O'Keefe, 1997, 1998) has been

Section D: Purpose and Objectives

In the proposed study, BCM investigators (Drs. Cuellar and Teten) and CDC staff (Dr. Teten and Ms. Holland) will not participate in data collection and will not have access to identifiable survey data. SafePlace staff (Dr. Ball, Ms. Rosenbluth and their staff) will be responsible for collection and management of identifiable data. Per guidance from the Department of Health and Human Services, SafePlace, as a function of its interaction with CDC, will obtain its own Federal Wide Assurance number. BCM IRB will be the IRB of record, as SafePlace and the Austin School District do not have an alternative IRB. The details of these roles are provided in Section F2.

Safe Place (http://www.safeplace.org/site/PageServer) is the organizational infrastructure through which Expect Respect Support Groups (ERSG) were developed and is the mechanism through which Expect Respect is implemented and disseminated in schools. ERSG are a targeted group intervention for the prevention of teen dating violence offered to at-risk students. Promising results from preliminary pre-post program evaluations suggest a controlled trial of ERSG is warranted.

This protocol seeks approval to collect students' survey response data for a controlled evaluation. As targeted and universal prevention programs are already implemented in Austin public schools and are considered a standard practice in this district (per legislative mandate), we are not seeking approval to conduct the intervention, but rather to collect and analyze survey data for research purposes.

The data will be used to examine one primary and two exploratory aims:

Primary Aim: To evaluate the effectiveness of ERSG to prevent and reduce teen dating violence perpetration and victimization and increase healthy relationship skills reported by at-risk male and female middle and high school students compared to at-risk students in control schools who do not provide ERSG.

Exploratory Aims: 1) To evaluate whether or not the effectiveness of ERSG is enhanced by the presence of a universal, school-wide prevention program. 2) To examine moderators and mediators of targeted and universal teen dating violence interventions, such as biological sex, history of peer and dating abuse at intake, and ability to identify abuse.

Hypotheses: Primary Aim: We hypothesize that ERSG participants will report less frequent dating violence perpetration and victimization and more frequent healthy relationship skills than students in the control group.

Exploratory Hypotheses: 1) In order to determine whether a universal prevention strategy produces positive effects above and beyond a targeted prevention strategy, we also seek to examine dating violence/healthy relationship behaviors among participants who receive a targeted prevention intervention only (ERSG) compared to those who receive both the targeted (ERSG) and universal (e.g., Safe Dates) prevention programs. We expect that students who receive the universal prevention strategy in addition to ERSG will not report significantly better outcomes than those who only receive ERSG. 2) Based on previous work, we hypothesize that students with recent peer and dating violence victimization and perpetration will evidence the greatest reduction in peer and dating violence perpetration and

Section E: Protocol Risks/Subjects

E1. Risk Category

(45 CFR 46.404) Category 1: Research not involving greater than minimum risk.

E2. Subjects

Gender:
Both

Age:
Adolescent (13-17 yrs), Child (3-12 yrs)

Ethnicity:
All Ethnicities

Primary Language:
English

Groups to be recruited will include:
Healthy, non-patient, normals

Vulnerable populations to be recruited as subjects:
Children, Students

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

In addition to the recruitment procedures outlined in Sections F2 and J2, several steps will be taken to protect the vulnerable population:

1) As the proposed study seeks to recruit at-risk students, and as SafePlace is a non-profit service organization, our recruitment procedures will seek referrals for any student who may need assistance with violence at home or in relationships. The intake interview/screening will have two functions: 1) to provide referrals to at-risk students and 2) to determine eligibility for the study. Therefore, any student in participating schools is eligible for an intake interview, but only those students who meet the inclusion/exclusion criteria will be given the option of participating in the study. For example, an 18 year old may undergo an intake and may be referred to community agencies for additional services, but would not be eligible for study participation.

2) Students will be assured in the intake session that the decision to participate in the study is voluntary, and in no way affects his/her ability to participate in other services.

3) Mandatory reporting requirements will apply to the intake session. In accordance with the Texas Family Code, facilitators will make a report if students report experiencing child abuse (mental/emotional injury, physical injury, sexual conduct harmful to a child, or neglect). If students report during the interview that they are perpetrating emotional, physical or sexual abuse of another child, that information will be reported by Safe Place personnel or AISD teachers to DPRS or the appropriate law enforcement agency. The Expect Respect policy for mandatory reporting is attached in Section S. As the identity of the victim and perpetrator is not collected on baseline, completion and follow up surveys that include questions about peer and teen dating violence, mandatory reporting will not apply to reports of violence made on the surveys. (As BCM investigators will not be involved in data collection or reporting, no Certificate of Confidentiality will be sought for the proposed study).

4) All students will receive educational materials about dating violence, and local and online resources (attached in Section S).

5) In the control schools, eligible students who are not in crisis but in need of no or minimal intervention will be eligible for the control condition. Regardless of their decision to participate in the evaluation, students from control schools in need of minimal intervention will be offered short-term individual psycho-education at school (1-3 sessions) by the Expect Respect facilitators. We believe that this minimal intervention represents an ethical "treatment as usual" but we do not expect that the control intervention will impede the possibility of detecting group differences.

6) Parental notification: Although a waiver of parental consent will be sought in the study (described in J1) participants in both study groups also will be given a parental information letter that they may choose to give to their parents.

7) Participant confidentiality: Participants will be assigned a code by Safe Place co-investigators or their staff. No information that could link a students' number to his/her data will be released to anyone outside of SafePlace. The use of random codes will also allow the PI, Dr. Amy Cueller, BCM volunteer faculty/CDC science officer, Dr. Andra Teten, and

E3. Pregnant woman/fetus

Will pregnant women be enrolled in the research?

No

E4. Neonates

Will neonates be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

Yes

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

d) Questionnaire/survey/interview

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

The proposed evaluation will use a quasi-experimental/non-randomized design. To address the primary aim, participants in middle and high schools receiving targeted prevention services (ERSG) are compared to students in control schools in which ERSG is not available.

Intervention schools will be selected from the Austin Independent School District (AISD), as ERSG are already underway in 24 of the 31 AISD schools. Approximately 10 control schools will be selected from three neighboring districts (Del Valle ISD, Manor ISD, and/or Pflugerville ISD) that have characteristics (e.g., demographics, socio-economic status and number of at-risk students according to data published by the Texas Education Agency) similar to the Austin ISD intervention schools.

Inclusion Criteria:

Intervention subjects will be students at middle and high schools providing ERSG and control subjects will be students from schools that do not offer ERSG. Only students from schools that have agreed in writing to participate in the study will be eligible. Within these schools, students in grades 6 through 12 ranging in age from 11 to 17 years will be eligible to participate in this study.

Participants who assent to the study must have a history of witnessing domestic violence, and/or experiencing child abuse (emotional/mental, physical, sexual, neglect) and/or being involved in abusive peer and dating relationships. Inclusion criteria for the proposed study will be assessed during the intake session.

Exclusion Criteria:

Exclusion criteria for the evaluation are having never experienced (i.e., been a victim, perpetrator, or witness of) any form of violence or requiring a higher level of care than the ERSG can provide. In other words, students in crisis (e.g., acute emotional upset, suicidal or homicidal ideations) will not be eligible. Students in crisis (at either intervention or control schools) will be referred for mental health, social and/or legal services.

Students younger than 11 or 18+ years old will be excluded. Our past work suggests very few 18 year olds participate in ERSG or are referred by teachers, so we expect that our exlusion of 18 year olds will effect very few students. Also, based on public records, very few 10 year olds are in middle school. Therefore our criteria should allow for most of the eligible middle and high school students to meet the age requirement.

F2. Procedure

INVESTIGATOR ROLES: Dr. Amy Cuellar, a faculty member at BCM, will serve as the PI of this study and point of contact for BCM IRB purposes. She will also serve as a no-cost psychological consultant for the study. Dr. Cuellar is a licensed clinical psychologist and has expertise in the development and treatment of mental illness, with emphasis in trauma-related sequelae. As at-risk students participating in the evaluation may have experienced trauma in the home or dating relationships, Dr. Cuellar will provide consultation to Safe Place personnel/ERSG facilitators, but not to students participating in the study, as needed, to address these issues. Dr. Cuellar has provided professional feedback on survey development, and she will provide input on proper survey administration and training tactics for Safe Place personnel. Dr. Cuellar will not participate in the collection or analysis of data. To protect the confidentiality of the participants, Dr. Cuellar will not have access to individually identifiable data or direct contact with study participants.

Dr. Barbara Ball and Ms. Barri Rosenbluth are staff members at Safe Place and will coordinate the Expect Respect evaluation. All Expect Respect facilitators will be Safe Place employees and will be responsible for administering surveys and collecting and coding data obtained from the surveys. In addition, Safe Place employees and teachers/staff at participating schools will be responsible for reporting child abuse. These reporting procedures are required by state and local agencies and have been included in this protocol only to emphasize measures that will be taken to ensure the safety of students participating in this study (see intake protocol in Section S).

Dr. Andra Teten, a co-investigator on this study is volunteer faculty at BCM and a science officer at the Centers for Disease Control and Prevention (CDC). She has provided professional insight on the development of surveys to be administered in this study. Dr. Teten will help to analyze deidentified data from the pre-test, post-test, 12 month, and 18 month surveys, which will be sent to her by Safe Place personnel. Ms. Kristin Holland (project officer) is an employee at the CDC, the funding agency. Per CDC policy for non-engagement, Dr. Teten and Ms. Holland will maintain oversight of the project and offer technical assistance, but will have no access to identifiable data and will have no contact with study participants. Deidentified data will be sent to Drs. Cuellar and Teten and Ms. Holland by Safe Place personnel.

NOTE: Data collection will not take place at BCM. The study is being conducted by Safe Place personnel in school districts in and around Austin, Texas. Safe Place has requested their own Federal Wide Assurance (FWA) number as a non-profit organization, per federal regulations for human subject research and will request approval to conduct this evaluation from AISD, which will require IRB approval before approval is granted. However, AISD is not associated with an IRB; therefore, BCM is to be the IRB of record, but SafePlace will have its own FWA number.

RECRUITMENT/REFERRAL: Expect Respect facilitators will provide orientation sessions for school staff to raise awareness about risk factors and warning signs of teen dating violence and to obtain referrals.

In intervention schools, ERSG will be advertised through posters and the school newsletter. Students will primarily be referred by school counselors and teachers, although self-referrals

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 0 Worldwide: 1800

Please indicate why you chose the sample size proposed:

Based on a past, uncontrolled program evaluation of Expect Respect Support groups, we anticipate that in the Austin ISD, 400 students will undergo an intake session, of whom 300 will be eligible for Expect Respect Support Groups, of whom 200 will complete the baseline and completion assessments.

Therefore during each year of data collection (2010-2011, 2011-2012, and 2012-2013 school years), we will aim to recruit 300 eligible students (could require 400 intakes) from the intervention schools and 300 (also potentially 400 intakes) students from the control schools for a total of 900 intervention and 900 control students.

Our power analysis is based on the following assumptions: 1) The unit of analysis for the study will be the school. We anticipate 24 AISD schools will participate in the intervention and 10 schools from neighboring districts will participate in the control group. 2) Based on the preliminary evaluation we expect approximately 10 participants in each intervention school each year and we expect 10-20 participants in each control school each year. 3) We anticipate that the frequency of dating violence between intervention and control schools will differ by 10% at the end of the intervention. 4) We anticipate that the intra-class correlation coefficient will be .01. Based on these assumptions our power is at least 83% with complete data from approximately 1000-1300 students.

Estimated power would be higher if differences between proportions were bigger, cluster size increased, or ICC were smaller. Although steps will be taken to retain students in the control and intervention groups, we expect some attrition based on the preliminary evaluation and conservatively anticipate complete data from 1200 of these students, which is consistent with our power analysis.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

Data analysis for our primary aim (examine group differences between control and intervention students) will involve: 1) descriptive analyses of group characteristics to examine prevalence and incidence of dating violence and chi-squared tests of independence with odds ratios to examine differences in prevalance of dating violence for control and intervention students. Study hypotheses will be examined in several ways depending on the unit of analysis (e.g., student, school, school district): 1) Parametric tests such as logistic regression will be used to examine group differences over time, 2) Nonparametric tests such as Wilcoxon rank sum test will be used to examine group differences on non-normal outcomes (e.g., sexual violence), and 3) structural equation modeling (panel and growth curve models) will be used to test for differences between intervention and control groups over time.

For logistic regressions and structural equation models we will take into account baseline differences on demographic characteristics, mediators, and dating violence outcomes for students who are lost to follow-up between baseline and follow-up. Variables found to differ between follow-up survey responders and nonresponders will be included as covariate in multivariate analyses of program effectiveness.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts and assess the likelihood and seriousness of such risks:

The risk of losing confidentiality is minimal and will be managed by assigning a random code to students (by Safe Place co-investigators or their staff), by SafePlace personnel not releasing any information that could link a students' number to his/her data, by storing personally identifying information in a locked cabinet, by using random subject numbers and not personally identifiable information in databases, and by emailing only de-identified datasets.

Subjects may experience slight emotional upset (i.e., anger, shame, embarrassment) associated with responding to questions about current or past victimization or perpetration. Expect Respect counselors will be available during the survey completion times to attend to emotional upset that, while possible, is unlikely.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

No

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefits to be gained by the individual subject as a result of participating in the planned work.

Five potential benefits exist for the students' participation. First, the participant will gain the experience of participating in a research protocol, which may be a valuable educational experience. Second, responding to the questionnaires in the proposed study may provide the participant insights into him/herself and may provide the impetus to seek help or other positive changes. Third, students will receive a list of prevention, family violence, dating violence, and mental health resources available in their area, should they choose to seek help for any of the issues assessed in the study (see Section S). Individual psycho-education (1 – 3 sessions) is available if a minimal intervention is indicated. Fourth, very few teen dating violence prevention strategies have been developed and implemented. Expanding the evidence base of effective teen dating violence efforts will lead to the development and implementation of effective intervention and prevention programs. Fifth, increased awareness of warning signs and risk factors of teen dating violence among school personnel will benefit students. However, the participant may obtain no benefit from participating.

Describe potential benefits to society of the planned work.

The assessment, treatment, and prevention of interpersonal violence are perhaps the most important and most difficult tasks facing students, parents, and teachers. The legal, interpersonal, social, physical health, and psychological consequences of violence are far-reaching and are a constant strain on individuals and society. Expanding the understanding of effective teen dating violence prevention programs builds the evidence base, a goal which will benefit youth who are at risk or who are already perpetrating or experiencing dating violence. The data collected from subjects will allow us to evaluate the ERSG program, which could provide strong support for the implementation of similar programs in schools with at risk student populations.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

This proposed work has a favorable risk-to-benefit ratio because (1) surveys may provide the participant with a deeper self-understanding, (2) students will receive a list of resources for violence prevention and mental health treatment, (3) participation in research may be a valuable learning experience, (4) results of the study have the potential to influence assessment, intervention, and prevention programs in clinical and community settings, and (5) the possible risks are minimal and typically transient.

Section J: Consent Procedures

J1. Waiver of Consent

Will this research require a waiver of consent and authorization?

No

Will additional pertinent information be provided to subjects after participation?

No

Explain why providing subjects additional pertinent information after participation is not appropriate.

Data collected will be used strictly for the purpose of evaluating the ERSG program as a whole. We do not anticipate any information after participation in the study to be pertinent to participants. However, all participants will have the opportunity to discuss questions arising from the surveys with the Expect Respect facilitators and they will all receive information and local resources for shelters, counseling and violence prevention programs.

J1a. Waiver of requirement for written documentation of Consent

Is this research subject to FDA regulations?

No

Explain how the research involves no more than minimal risk to the participants, and the specifics demonstrating that the research does not involve procedures for which written consent is normally required outside of the research context.

Explain how the only record linking the participant and the research would be the consent document, and how the principal risk would be potential harm resulting from a breach of confidentiality, and how each participant will be asked whether he or she wants documentation linking the participant with the research and their wishes will govern.

J2. Consent Procedures

Who will recruit subjects for this study?

Third Party: Expect Respect facilitators and School staff

Describe how research population will be identified, recruitment procedures, and consent procedures in detail.

Only students age 11-17 at participating middle and high schools will be recruited.

At both control and intervention schools, Expect Respect facilitators will provide orientation sessions for school staff to raise awareness about risk factors and warning signs of teen dating violence, and to obtain referrals. Students will be primarily referred by school counselors and teachers, although self-referrals may occur as well.

In intervention schools, ERSG will be advertised in the school through posters, and the school newsletter.

In control schools, students will have the opportunity to talk to an Expect Respect facilitator about peer and dating violence and healthy relationships and to participate in a study. The study also will be advertised in the school through posters and the school newsletter.

In intervention schools: When a student is referred to Expect Respect facilitators, an intake session will be completed during which the counselor determines the student's eligibility for support group participation (see inclusion/exclusion criteria in F1 and section S for intake protocol and screening form). At the end of the intake session eligible students will be given information about ERSG and asked if they are interested in participating. Participation in ERSG is voluntary. If the student gives his/her assent to participate in the program, he/she will then be told about the evaluation. It will be explained that the decision to release their de-identified survey responses for this research is voluntary, and that the decision to assent to the evaluation in no way affects his/her ability to participate in ERSG or other prevention services. Following this discussion the facilitator will obtain informed assent from the students. Students will also be informed that they may rescind their assent to release their data for any reason at any time.

In control schools: When a student is referred to Expect Respect facilitators and intake session will be completed during which the facilitator determines the student’s eligibility for participation in the study (see inclusion/ exclusion criteria in F1 and section S for intake protocol and screening form). At the end of the intake, students eligible for the control condition will be given information about the evaluation and asked if they are interested in completing surveys as part of the control condition. If the student is interested, it will be explained that the decision to complete the surveys and release their data is voluntary, and that the decision to consent to the evaluation in no way affects his/her ability to participate in community-based prevention or other services (e.g. 1 – 3 psycho-educational sessions or referrals for more intensive services). Following this discussion the Expect Respect facilitator will obtain informed assent. Students will also be informed that they may rescind their assent to release their data for any reason at any time.

All students will receive a packet of educational materials about dating violence, local and online resources (see Section S).

Although, waiver of parental consent will be sought in the study to protect the welfare of the at-risk students (described attachment J4) participants in both intervention and control schools will be given a parental information letter (in Section S) that they may choose to give to their parents.

Are foreign language consent forms required for this protocol?

No

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

Yes

J4. Children

Will children be enrolled in the research?

Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?

No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?

No

J7. Prisoners

Will Prisoners be enrolled in the research?

No

Section K: Confidentiality

Will research data include health information by which subjects can be identified?

Yes

Where will research data be kept? How will such data be secured?

Data will be stored at the Resource Center at SafePlace (1515A Grove Blvd., Austin, TX 78741). Data will be double locked in a file cabinet with a locking mechanism and in an office with a locked door.

De-identified datasets may be emailed to the investigators for the purpose of data analysis, but no information that could be used to identify the subjects will be included in these data.

Who, besides the PI, the study staff, the IRB and the sponsor, will have access to identifiable research data?

Access to identifiable research data will be restricted to Expect Respect/SafePlace staff or IRB.

BCM PI, Amy Cueller; CDC science officer, Andra Teten; and CDC project officer, Kristin Holland (IRB Administrative Contact), will remain "non-engaged" in the research, meaning that they will never be able to link the participants' data to their identity. The only people who will have access to identifiable research data are Expect Respect staff.

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

There will be no cost to the participant.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

40

Distribution Plan:

Both control and intervention group participants will receive the first $10 mall gift card upon completion of the baseline survey, another $10 mall gift card for the 8-month/program completion survey, and a $10 mall gift card for each follow-up survey.

All incentives will be distributed in the form of gift cards to protect the confidentiality of the students.

To ensure equitable resources/services are being provided to both intervention and control schools, and to offset the administrative burden placed on the control schools, an incentive (one-time payment of $1000) will be offered to control schools to participate in this study. Past work suggests that offering incentives to control schools facilitates the schools likelihood of participating in research.

Intervention schools will not be offered the incentive, because they will receive prevention services from SafePlace and will benefit from the implementation and evaluation of the ERSG program.

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Is this study placebo-controlled?

No

Does the research involve a drug or biologic (including radioactive drugs) that is not approved by the FDA?

No

Will the research involve a radioactive drug that is not approved by the FDA?

No

IND Number:

Section P: Device Studies

Does this research study involve the use of ANY device?

No

Section Q. Consent Form(s)

None

Section R: Advertisements

ADVERTISEMENT: Other: flyer and newsletter

Exact language of Advertisement:

All flyers are attached in Section S. The language below (and the flyers) would be posted in the schools or would appear in the student newsletter.

#1 for Intervention schools:

CONFUSED ABOUT YOUR RELATIONSHIP? Do you have questions about love? Do you get jealous easily? Do you have a hot temper? Have you hurt someone you cared about? Is there violence in your home? Check out the Expect Respect groups. Ask your counselor for information.

#2 for Intervention schools:

Have you ever been with someone who… Tried to control you? Told you what to wear? Scared you at times? Pushed or hit you? Was very jealous? Called you names? Check out the Expect Respect groups. Ask your counselor for information.

#1 for Control schools:

CONFUSED ABOUT YOUR RELATIONSHIP? Do you have questions about love? Do you get jealous easily? Do you have a hot temper? Have you hurt someone you cared about? Is there violence in your home? Ask your counselor for information.

#2 for Control schools:

Have you ever been with someone who… Tried to control you? Told you what to wear? Scared you at times? Pushed or hit you? Was very jealous? Called you names? Ask your counselor for information.

Memorandum

Date June 7, 2010

From

LaShonda Roberson, MPH

LT, USPHS

IRB-B Administrator

Human Research Protection Office

Subject

CDC Approval of New Protocol 5937.0, "Controlled Evaluation of Expect Respect Support Groups."

(Expedited)

To

ANDRA TETEN, PhD

NCIPC/DVP

CDC's IRBB has reviewed the request for approval of new protocol5937.0, "Controlled Evaluation of Expect Respect Support Groups," and has approved the protocol for the maximum allowable period of one year. CDC IRB approval will expire on6/3/2011. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories 4 and 7.

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol

for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the protocol's expiration date of 6/3/2011.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-4721 or email at huma@cdc.gov).

CC:

NCIPC Human Subjects