(For ORP use only) BC IRB Protocol#: 22.037.01

Boston College Institutional Review Board
Office for Research Protections
140 Commonwealth Ave., Waul House
Chestnut Hill, MA 02467
(617) 552-4778 Fax: (617) 552-0498 E mail: irb@bc.edu

INITIAL IRB APPLICATION FORM

For Initial IRB Review Only

I. Study Title: (If funded must match the sponsored title)	Preventing Alcohol and Other Drug Use and Violence among Latino Youth - Clinical Trial	**Today's Date:** 06/30/21

II. Principal Investigator Information

A. Name of Principal Investigator	Christopher Salas-Wright		B. Are You? (Please check)
			◉ Faculty
C. Mailing Address:	140 Commonwealth Ave McGuinn Hall, #218 Chestnut Hill, MA 02467		○ Staff
			○ Undergraduate Student
D. Department:	Social Work/ Graduate School of Social Work		○ Graduate Student
E. E-mail address:	wrightcu@bc.edu		
F. Primary Phone Number:	(617) 552-4020	G. Alternate Phone:	8572124049

III. Research Risk

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46. 102). Research must present no more than minimal risk to human subjects in order to qualify for exempt or expedited review. Research must fit within one of the categories of review in order to qualify for that level of review.

Projects that propose greater than minimal risks to human subjects are considered full board protocols and they must be reviewed by the IRB at a convened meeting. The IRB meetings are held every third Wednesday of the month. Full board protocols must be submitted ten business days in advance of an IRB meeting in order to be reviewed at that month's meeting. ***NOTE:*** *Research involving prisoners is always considered a full board protocol and must be reviewed at an IRB meeting.*

A. Does the research propose greater than minimal risk to participants? ○ **Yes** ◉ **No**
B. Does the research include prisoners? ○ **Yes** ◉ **No**

C. Level of Review

Please select a level of review and the appropriate category that corresponds to that level of IRB review:

- ☐ Exempt
- ☑ Expedited *Category Number*: 6, 7
- ☐ Full Board

IV. General Study Information

Is this project a *Clinical Trial*? ◉ Yes ○ No

A. Funding

1. ☐ **None** (Go on to Section B)

2. ☐ **University Funded**
3. ☐ **External**
4. ☑ **Federal** : List agency: NIAAA

☑ Sponsor Award Number (if known)
1 K01 AA026645-02
☐ BC Project Number (if known)
Not known

5. Is BC the primary awardee for the grant? ◉ Yes ○ No
6. Are there subcontracts? ○ Yes ◉ No

B. Participant Recruitment Numbers: This number must be the maximum number you intend to recruit. You will not be allowed to recruit more than this number without first coming back to the IRB to seek approval.
Total # of participants: 50
Do you plan to include a larger proportion of one gender group, or omit any gender groups? ○ Yes ◉ No

C. Participant Ages (please check)
- ☐ 0-7 (parental consent and oral child assent)
- ☑ 8-11 (parental consent and child written consent)
- ☑ 12-17 (parental consent and written consent)
- ☐ 18-65
- ☐ 65+

D. Estimated Project Duration
Start Date: 07/01/21 End Date: 08/31/23

E. Why is this Project being conducted? (please check)
- ☑ Faculty/Staff Research
- ☐ Undergraduate Coursework
- ☐ Master's Thesis
- ☐ Doctoral Dissertation
- ☐ Other:

F. Will This Study Involve Long-Term Follow-Up with participants: ◉ Yes ○ No
If Yes, please describe:

There will be a 6-month post-intervention survey data collection and follow-up focus group.

G. Special Study Populations
- ☑ Minors (under 18 years) If including minors, also complete Research with Minors Form
- ☐ Pregnant Women/Fetuses or products of labor & delivery
- ☐ Prisoners
- ☐ Physically or mentally challenged
- ☐ Diminished capacity for consent
- ☐ Other:
- ☐ No Special Study Populations

H. Does this study involve any of the following?

- ☐ Deception or Punishment
- ☐ Use of drugs
- ☐ Covert observation
- ☐ Induction of mental and/or physical stress
- ☐ Procedures which may risk physical/mental harm to the participant
- ☐ Materials/issues commonly regarded as socially unacceptable
- ☐ Information relating to sexual attitudes, sexual orientation or practices
- ☑ Information relating to the use of alcohol, drugs or other addictive products
- ☐ Procedures that might be regarded as an invasion of privacy
- ☐ Information pertaining to illegal conduct
- ☐ Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.
- ☐ Information normally recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.
- ☑ Information pertaining to an individual's psychological well being or mental health.
- ☐ Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.
- ☐ None of the above Procedures

Please provide details on all procedures checked above: How are they integral to the study?

The study is an substance use intervention study; thus collecting information about AOD use is important to measure effectiveness of the intervention. Additionally, anxiety and depression will be measured as they are commonly comorbid with substance misuse and are important cofounding variables to determine the effectiveness of the intervention.

V. Research Summary:

Instructions: A research summary is a narrative that provides the IRB with important information about a study. Please provide a thoughtful response to each section using simple language and avoid technical jargon. If a specific question is not applicable to your study, please state not applicable or n/a .

A. Introduction and Background:

1. State the problem and hypothesis

There are currently no interventions aimed at preventing both alcohol and other drug (AOD) use and interpersonal violence that have been adapted for Latino adolescents. This study hypothesizes that a cultural adaptation of a validated AOD use prevention program (Keepin' it REAL) that also integrates violence prevention content will both amplify the AOD use effects of that intervention for Latino adolescents and lead to reductions in youth violence.

2. Provide the scientific or scholarly reason for this study and background on the topic

Adolescent alcohol and other drug (AOD) use and interpersonal violence impose major social costs. These behaviors are also profoundly interrelated. Youth substance users are more likely to enact violence and prospective studies have shown that youth involvement in violence predicts later AOD use. It is believed that both are connected to similar underlying biosocial processes. Latino adolescents have been found to be disproportionately at risk for involvement in both substance use and violence. Latinos are also the fastest growing segment of the adolescent population, and it is predicted that the proportion of the youth population that is Latino will continue to rise in the foreseeable future. Certain Latino populations, such as Venezuelan immigrants, are rising especially quickly. There is a thus a need for culturally-concordant interventions to prevent or delay initiation of both AOD use and interpersonal violence among this population.

Furthermore, the cultural adaptation literature indicates a need for more finely-grained adaptations and has encouraged focusing on more specific groups, as Latinos represent a large and diverse array of cultural backgrounds. To this end, this project will focus on Venezuelan immigrant youths. Due to the political and socioeconomic changes in Venezuela over the past several years, over 5 million Venezuelans have left their country since 2015. Cross-sectional research has found elevated psychosocial risk factors and rates of alcohol misuse among that population, indicating that they are priority population for youth prevention efforts. The initial phase of this project, which consisted of qualitative focus groups with Venezuelan migrant youth, indicated that interpersonal aggression for this population is frequently mediated through social media and online platforms, so special attention to interpersonal violence in the cyberspace will be integrated into the intervention.

B. Specific Aims/Study Objectives:

1. List the purpose(s) of the study (what are you hoping to learn as a result of the study)

The purpose of this study is to conduct a pilot-test randomized controlled trial (RCT) of a youth AOD use prevention intervention that has been adapted to integrate interpersonal violence content and has been culturally adapted for a specific Latino population (Venezuelan migrant youth). The goals of the pilot test are to determine feasibility, acceptability, and preliminary effects of the intervention for future testing.

The intervention will be an adaptation of Keepin' it REAL (KiR). KiR is a 10-week intervention for early adolescents that is considered a model evidence-based AOD use prevention program by SAMHSA. It based on communications theory and the importance of aligning cultural values with AOD outcomes. Weekly sessions focus on teaching youth communications strategies to enhance their ability to navigate situations where substance use may be present. It incorporates a student workbook, videos, and in-session discussions and exercises. We will be adapting the intervention for an online platform so that it can be delivered virtually. We will also be integrated interpersonal aggression content to expand the logic and program theory of KIR to apply to situations in which violence may arise. The goal is to both delay initiation of AOD use/aggressive behaviors and change the youth's norms around the appropriateness of AOD use and interpersonal aggression. The intervention will delivered for the pilot study by members of the research team (PI and/or GRAs). The intervention materials will be translated into Spanish by a research team member who is a native speaker of Spanish and checked for accuracy by other members of team. Adaptations will be made in consultation with a community advisory board that consists of Venezuelan migrants to check for cultural fit, language appropriateness, and overall concordance with the target population. All members of the research team are either fluent or proficient in Spanish.

A three-armed RCT design will be used. In addition to a control group that will receive an abbreviated, one-session workshop, one group will receive a version of the intervention that has been adapted for Venezuelan youths and the other will receive a version of the intervention that has been adapted for Venezuelan youths and includes interpersonal violence content. The purpose of this design is to determine the effectiveness of the the culturally adaption of KiR for the original intended outcome (reduced AOD use) and the separate effect of integrating interpersonal violence content on reducing aggressive behaviors.

C. Materials, Methods and Analysis (quantitative and qualitative)

1. Describe data collection methods (Procedures) (be specific)**:**

Data will be collected both prior to and after the intervention. Data will be collected a pre-test prior to the intervention, which is a 10-week program consisting of weekly online sessions to provide psychoeducation and skills training regarding avoiding substance use and interpersonal aggression. The control group will participate in a one-time skills-building workshop but data will be collected at the same timepoints. Please see intervention materials included as supporting documents for more details. Data will then be collected at two time points following the intervention - immediately after and at 3 months follow-up.

Data will be collected via self-report survey using Qualtrics. The survey will be administered via Qualtric's email function and each participant will receive a unique link. The survey will be administered in Spanish although an English version will be available if preferred. The survey will be translated into Spanish by a research team member who is a native speaker of Spanish and checked for accuracy by other team members who are also fluent in Spanish. Cognitive interviews will be conducted with community advisory board members to determine intelligibility and cultural sensitivity of the survey. Only approved members of the research team will have access to the Qualtrics account and downloaded data will be kept in a secure database.

Focus groups will be conducted with participants after the final wave of data collection. Focus groups will focus on understanding how youth experienced the intervention program. This will be based on three core questions: What did you like/dislike about the program? What parts of the program were especially helpful/unhelpful? What would you suggest we change? Focus groups will be conducted online and recorded for transcription. **Zoom settings will be adjusted to ensure audio recordings of focus groups will be downloaded directly onto the researcher's device rather than to cloud storage.** All data collection - including surveys and focus groups - and the intervention itself will be implemented by research staff who are either qualified social workers or social work students and all of whom are either native speakers of Spanish or fluent Spanish-speakers with experience using Spanish in professional settings.

2. Describe the specific materials or tools that will be used to collect the data (be specific)**:**

Survey will consist of items to gather information related to: demographics; technology access & use; cigarette, alcohol, and cannabis use; interpersonal aggression; depression & anxiety; norms regarding AOD use; and norms regarding interpersonal aggression. These items have been adapted from previous evaluation studies of KiR.

Focus groups will be conducted over Zoom and recorded for transcription. **The computer where the Zoom recordings will be temporarily stored will be password-protected.**

3. Describe timeline of the procedures and how long each procedure will last

Survey data will be collected at baseline, immediately following the intervention, and at 3 months post-intervention follow-up.

The same survey instrument will be used at all three data points. The intervention is anticipated to take place in fall 2021, with post-intervention data being collected in spring 2022. This timeline may be earlier depending on the speed of recruitment. The survey takes approx. 30 minutes to complete.

Participants will be invited to participate in a focus group after the final wave of data collection in spring 2022.

4. Describe how you will analyze your data (be specific)**:**

Exploratory descriptive analyses will be performed initially to examine variable distributions, confounding variables, and missing data. The primary analysis will be determining retention rates across all three data collection timepoints in order to establish feasibility of the intervention. The secondary analysis will examine the effect sizes between the two intervention groups and the control group will be determined regarding changes in AOD use, interpersonal violence, and norms for AOD use/interpersonal violence across the three waves of data collection.

Transcriptions will be open-coded for thematic analysis using grounded theory techniques.

D. Research Population & Recruitment Methods:

Describe:

1. Inclusion and Exclusion Criteria (what participant traits are needed to be included, what traits exclude participants?)

Inclusion criteria are 1) being born in Venezuela, 2) currently residing in the U.S., and 3) being between the ages of 11-14 at the time of recruitment. Participants will also need access to the internet and technology to complete the surveys and participate in the intervention. AOD use and/or engagement in interpersonal aggression will not be considered for purposes of inclusion/exclusion, unless the participant is intoxicated to the point of being unable to successfully complete a survey or participate in the intervention. Participants will also be excluded if they are otherwise cognitively unable to successfully engage in the intervention. **The GRA who is consenting the participant will determine capacity. All GRAs who will be consenting participants will be either clinical MSW students who have experience performing mental health assessments or licensed mental health professionals. The GRAs who are licensed mental health professionals will also be available to consult with the student GRAs as needed. If there are questions or concerns about capacity to consent, final determination will be made by the PI.**

2. What is the scientific or scholarly justification for the number, gender, age, or race of the population you intend to recruit?

Early adolescence is a critical developmental window. AOD use and aggression in early adolescence have been linked to higher risks for later negative psychosocial outcomes, including substance use disorders, thus making it an important life stage in which to intervene. Furthermore, the empirically-validated intervention that is being adapted (KiR) is aimed at early adolescents (specifically 7th graders), so a similar age group will be recruited to maintain treatment fidelity.

3. How did you choose the source of participants or data? (census records, BC students, Mass General Hospital records, etc.)

Participants will be recruited via a community partner in Miami, FL, that provides social services for Venezuelan immigrants (Raices Venezolanos). Our community partner will be asked to refer local youth to the study.

4. Recruitment procedure; including who will recruit participants and, if applicable, how any conflict of interest/coercion/undue influence will be mitigated

The research team will recruit participants in conjunction with the community partner in Florida. Specifically, our community partner will inform parents about the opportunity to participate and the research team will then communicate with parents and kids. We will then select participants in the order that they express interest, enrolling only those who have received informed consent and provide assent. Our point of contact is with parents who will be told about the study and will then have the discretion to proceed with informing their children about the possibility of participation. We will specifically instruct our community partners that participation must be voluntary and free of coercion, and we too will communicate this verbally and in our consent documents. We will communicate to our community partner that it is critical that youth have the freedom to tell partner agencies that they prefer not to participate. Please note that our community partner will NOT be consenting participants--as such, we are in a position to ensure that all youth participate without coercion. Although the our primary community partner is not a member of the research team for this project, she has completed CITI training and has previously received instruction from the PI concerning human subjects research, coercion, etc. All recruitment is via word-of-mouth. Recruited participants may also be asked to refer other potential participants.

5. Tools that will be used to recruit (payment, advertisements and flyers attach copies to this application)

A recruitment flyer will be used to facilitate recruitment by the community partner and to provide essential details of participation in the study.

6. Research Incentives and Payments: Please specify what form of payment you will be using and how it will be documented. (Note: participant payment beyond $600 must be reported to the IRS, and this requirement must be added to the consent form)

Participants will receive incentives for both completing the surveys and participating in the intervention. Participants will receive a $30 gift card for each survey completed, for up to $90 total per participant. Gift cards will be distributed via Tango Card, a third-party vendor that integrates into Qualitrics, which will document who has completed the survey and received a gift card. Participants will receive a Boston College item (such as a teeshirt) worth approx. $30 for their participation in the intervention itself. If participants withdraw early from the intervention they will still receive the item in appreciation for their time. Distribution will be tracked by the PI/GRAs using a spreadsheet. Research team members will manage to the greatest extent possible the incentive distribution process. Program administrative staff will only be involved if needed and only be provided de-identified information.

Participants will also receive a $30 gift card for participating in the focus group. They will receive the gift card even if they leave the group before it finishes.

E. Informed Consent Procedure:

1. Who will perform the informed consent procedure, and how will that person be trained? (*Note:* undergraduates should specify their qualifications and describe how the faculty research supervisor will closely monitor.)

Informed consent will be performed by the PI/GRAs. PI will train the GRAs in best practices for consenting the participants and their parent/guardian and oversee the informed consent process.

2. How will the prospective participant's competence or understanding of the procedures be assessed; will participants be asked questions about the procedures, or encouraged to ask questions?

Parents/guardians and the child will have the study explained to them verbally and be encouraged to ask questions. They will receive an electronic copy of the informed consent document in Spanish via email. The document will be translated into Spanish using the same process as the survey and intervention materials, first by a member of the research team who is a native speaker of Spanish and then checked by other members of the research team who are fluent in Spanish (or also native speakers).

3. Please describe the process by which informed consent will be obtained. ***Note: research involving minors requires consent from a parent/legal guardian and assent from the child.***

A research team member will meet with each participants and his/her parent/guardian(s) prior to the initiation of the intervention to screen for appropriateness and to collect informed consent. These meetings will be conducted in either English or Spanish as preferred by the participant and their family. Informed consent will include both the survey data collection and participation in the intervention itself. Informed consent will be documented via Qualtrics due to public health guidelines around social distancing and the virtual nature of the intervention. They will indicate verbally and via Qualtrics that they understand the study procedures and agree to participate.

F. Confidentiality:

Describe the Provisions for participant and data confidentiality:

1. Where will the data be stored, and who will have access to the data and the area? (**Please refer to the *References Tab* for the latest BC Research Data Policy.)**

The data will be stored on a secure departmental server administered by BC. Only IRB-approved members of the research team will have access to the password-protected server.

2. How will the data be stored, and in what format (hard or electronic copy, identifiable or de-identified)

Data will be stored electronically. It will be identifiable since participant data will need to be linked across the three waves of data collection. Survey data and focus group transcripts will be de-identified. Focus groups recordings will be deleted after transcription.

3. Will you collect the names, email addresses, phone numbers, student ID numbers, and/or any other data elements that individually identify the subjects of the research? Will the participant's identity be coded? Will the codes to

identify participants be stored with the data?

Participant's names and emails will be collected. Participants will be assigned a unique, randomized code by Qualtrics upon completion of the informed consent. The sheet with names and codes will be kept in a password-protected spreadsheet that will be stored separately from other data. Only two members of the research team (the GRA handling survey distribution and the PI as a back-up) will have access to the spreadsheet with names and emails.

All data will be deleted one year after the end of the study (August 2024).

4. Will you collect any identifiable information from any organizations or individuals other than the subjects (or potential subjects) **themselves?** (e.g., a hospital or school) ○ Yes* ◉ No

G. Statement of potential research risks to subjects (e.g. breach of confidentiality, treatment complications)

1. Indicate the type of risk that may result from participation. Consider psychological or emotional risks, social stigma, change in status or employment, physical risks or harms, information risks-breach of confidentiality and any effect loss of confidentiality may have on status, employment, or insurability. If the protocol involves treatment, what are the risks compared to other treatments in terms of "standard of care"? *Please consider any populations who may be particularly vulnerable and may be triggered by this research topic and the risks they may face. Please check section IV.H. to ensure that you have considered how sensitive topics might lead to risks for some populations.*

We anticipate minimal risk to participation in both the survey data collection and the intervention. Participants may have feelings of discomfort in providing information requested on the survey. The research team cannot provide a secure space for to complete the survey so there is a chance that others may see their responses. For participants in the intervention, they may feel social pressure to share information they do not want to and what is shared in the groups may divulged by other group members. There is no reasonable risk of loss of employment or insurability.

2. Consider the likelihood and magnitude of the risks or discomforts occurring? Are they unlikely, or likely to occur and what effect would the discomforts or risks have on the individual should they occur?

The magnitude of risks are minimal and overall unlikely to occur. The most likely main effect would be feelings of embarrassment on the part of the participant. However, we take seriously the possibility of breach of confidence and will do everything possible to minimize this risk.

3. How will you minimize the risks? Some examples include informed consent, adequate staff training and experience, debriefing, and monitoring adverse effects on participants

The intervention will focus on skills-development and hypothetical scenarios to avoid having the participants feel pressured to share personal experiences. The need for privacy to complete the surveys will be stressed in the informed consent process. Intervention facilitators (who will be members of the research team) will be trained to not pressure participants into sharing more than they feel comfortable. Intervention facilitators will also stress the importance of confidentiality with group members. The PI is a trained social worker with experience overseeing research teams who will train and supervise intervention facilitators on recognizing and managing participant distress. One of the GRAs is also a licensed mental health clinician will extensive crisis intervention experience who will be available for consultation and support as needed.

H. Statement of potential research benefits to subjects (Please note that compensation/ payments are considered a recritment tool and should not be listed as a benefit)

1. Indicate the type of benefit that may result from participation. Consider psychological or emotional benefits, learning benefits, physical benefits and discuss if participant will benefit directly or if the benefit is largely to gather generalizable knowledge or provide scientific or social information on a topic that may benefit society. DO NOT OVERSTATE the benefit.

For the participants receiving one of the versions of the intervention, they will benefit directly by learning new communication strategies to help navigate social situations where AOD use is present and to avoid interpersonal violence. The participants in the control group should benefit from the one-time psychoeducation workshop. All participants may benefit indirectly by contributing to the scientific development of an intervention for their community.

2. Consider the likelihood of the benefits. Will all or some participants benefit?

All participants are equally likely to gain benefit from participation in the various interventions, although those randomized to the full intervention may receive greater benefit. All can potentially benefit from feeling like they are contributing to an intervention to help their community.

I. Investigator experience. Please attach a current copy of your C.V. unless a current copy is on file. Note: the IRB only needs the C.V. from the PI, not the faculty advisor.

VI. Informed Consent

1. If this project qualifies for Exempt review, category 4 (previously collected data), or Informed Consent is otherwise not applicable click here ☐ and skip to section IX.

2. Are you requesting an alteration or waiver? ○ Yes* ○ No ◉ Both - I have a consent form, but will be asking for a waiver for some cases

A. Standard Elements of Consent
The informed consent document should include all required elements of consent (See BC Consent Guide for informed consent samples *https://www.bc.edu/content/bc-web/research/sites/vice-provost-for-research/research-protections/forms---templates.html*) . **Confirm that each element is included in your consent form** :

☑ A.1. A statement that the study involves research
☑ A.2. The purpose of the research in lay terms (in language understandable to the participant)
☑ A.3. A statement that they are being asked to participate in research, and how they were selected to participate
☑ A.4. The expected duration of the participant's participation "You will be asked to complete a survey every month for 1 year"
☑ A.5. The total time commitment of participation in the procedures "the survey will take 20 minutes to complete"
☑ A.6. A brief but complete description of all procedures to be followed (if research includes treatment describe which procedures are experimental and alternatives to those procedures)
☑ A.7. The risks or discomforts that are reasonably expected from the research, and a statement that "There may be unknown risks"
☑ A.8. The benefits to the participant or others that are reasonably expected from the research
☑ A.9. A statement of confidentiality that provides the participant a contact at the institution who may be reached if injury occurs or confidentiality is breached (this should be someone other than the researcher)
☑ A.10. A statement that participation is entirely voluntary and may be discontinued at any time
☑ A.11. A statement that withdrawal from participation will not result in denial of entitled benefits
☐ A.12. Invasive biological, clinical or behavioral interventions require specific descriptions of the procedure (Do NOT check this box if your study does not involve invasive biological, clinical, or behavioral interventions)
☑ A.13. The consent form must be signed and dated, or oral consent must be witnessed and signed and dated by the witness
☑ A.14. A statement and check box that indicates the participants have a copy of the informed consent document

Note: Individuals with added protections require both permission of a legal representative and assent of the individual.

B. Consent Waiver/Alteration: In rare circumstances, the IRB may consider altering the informed consent requirements. In order for the IRB to approval a waiver of the informed consent process or a partial waiver of any of the required elements of consent, require that: (*Federal Regulations: 45 CFR 46.116(d)(1-4)*

1. The research involves no more than "minimal risk;"
2. The waiver will not adversely affect the rights and welfare of the research participants;
3. The research could not practicably be carried out without the waiver; and
4. Whenever appropriate, the research participants will be provided with additional pertinent information after participation.

B.1. Are you asking for a partial waiver of consent: ◉ Yes ○ No

Please indicate which elements you are asking to waive::

☐ B.1.a. A statement that the study involves research
☐ B.1.b. The purpose of the research in lay terms (in language understandable to the participant)
☐ B.1.c. A statement that they are being asked to participate in research, and how they were selected to participate
☐ B.1.d. The expected duration of the participant's participation "You will be asked to complete a survey every month for 1 year"
☐ B.1.e. The total time commitment of participation in the procedures "the survey will take 20 minutes to complete"
☐ B.1.f. A brief but complete description of all procedures to be followed (if research includes treatment describe which procedures are experimental and alternatives to those procedures)
☐ B.1.g. The risks or discomforts that are reasonably expected from the research, and a statement that "There may be unknown risks"
☐ B.1.h The benefits to the participant or others that are reasonably expected from the research
☐ B.1.i. A statement of confidentiality that provides the participant a contact at the institution who may be reached if injury occurs or confidentiality is breached (this should be someone other than the researcher)
☐ B.1.j. A statement that participation is entirely voluntary and may be discontinued at any time
☐ B.1.k. A statement that withdrawal from participation will not result in denial of entitled benefits
☐ B.1.l Invasive biological, clinical or behavioral interventions require specific descriptions of the procedure

☑ B.1.m. The consent form must be signed and dated, or oral consent must be witnessed and signed and dated by the witness
☐ B.1.n. A statement and check box that indicates the participants have a copy of the informed consent document

Note: Individuals with added protections require both permission of a legal representative and assent of the individual.

B.2. Are you asking for a total waiver of consent: ○ Yes ◉ No

B.3. Are you asking for a waiver of the documentation of consent ◉ Yes ○ No

B.3.a. Are you asking for a waiver of the documentation of consent to waive the requirement for signature and name because this study will be conducted online: ◉ Yes ○ No

B.4. Please describe what elements of consent you wish to waive and provide a strong rationale for this alteration/waiver.
We wish the waive the requirement for a physical signature. The study will be conducted online and our target population has limited access to printers/scanners. We will document informed consent via Qualtrics instead will all the required elements.

C. The PI is responsible for ensuring that the consent form is written at a reading level that is appropriate to the population being studied. The comprehension level of the consent document must be verified by choosing one of the three readability tools below. Mark which tool you used to check the readability level of the consent form and insert the readability comprehension level (the grade level, 8.0,8.1, not the larger number) in the box below:

C.1. *http://www.readability-score.com/* ☑
C.2. *http://www.online-utility.org/english/readability_test_and_improve.jsp* ☐
C.3. Microsoft Word Readability Statistics ☐

C.4. Insert Readability Comprehension Level 5.8

VII. Research with Minors

Instructions: Please complete this section only if you are using minors in your research. Otherwise, you may proceed to the next section. Research with minors requires either expedited or full board review.

Federal regulations recognize children as vulnerable subjects in research and require that special consideration be given to protecting their welfare. IRBs consider the potential benefits, risks, and discomforts of the research to children as well as their circumstances (e.g. age, health status, ability, etc.) and assess the justification for their inclusion in the research (*www.hhs.gov*).

Please provide a scientific or medical rationale for the inclusion of minors:
Early adolescence is a critical developmental period and substance use initiation or interpersonal violence in this period can have serious ramifications for the adolescent's development and future psychosocial outcomes. Furthermore, early adolescence is when peer influences play a more prominent role in decision-making underscoring the importance of teaching communication strategies for navigating social situations that may lead to AOD sue and/or aggression. It is important to intervene during this age range to prevent more serious problems occurring later. Furthermore, the intervention being adapted (KiR) was developed and validated with early adolescents, so it is important to implement this study with the same age group to ensure treatment fidelity.

Federal regulations classify research with minors into four categories based on the degree of risk. Please pick the appropriate category for your research.
☑ Category 1 **(45 CRF 46.404)**: Research involving minimal risk to minors
My research falls under this category because:
Survey data collection does ask about substance use and aggressive behaviors but that information is confidential and only accessible by the research team. The intervention itself uses examples and hypothetical scenarios to teach skills and does not ask participants to disclose their own experiences with substance use or interpersonal violence. Participants will be encouraged to actively participate in the intervention but will not be pressured to share personal details that may make them uncomfortable.
Are the risks involved in participating in this research those that parents would allow their minors to experience in the course of their everyday lives? ◉ Yes ○ No
Are adequate provisions in place for soliciting the assent of the minors and consent from the parents? **(45 CFR 46.408)** ◉ Yes ○ No
☐ Category 2 **(45 CFR 46.405)**: Research involving greater than minimal risk to minors with the prospect of direct benefit to the child:
☐ Category 3 **(45 CFR 46.406)**: Research involving greater than minimal risk with no direct benefit to the minors but it is likely to yield generalizable knowledge about the subject's disorder or condition
☐ Category 4 **(45 CFR 46.407)**: Research not meeting the criteria for Categories 1-3 that involves greater than minimal risk to healthy minors and presents no direct benefit to them but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare. *Please note: this fourth category of research with minors requires a special level of DHHS review after BC IRB review.*

Guidance on Remuneration: Minors may receive small gifts of appreciation for participation. Gifts should rarely be cash and should never be contingent upon study completion. Parents and guardians may be compensated for travel or time lost from work.

VIII. Performance Sites:

If you are conducting research at a site, (e.g. hospital, school, organization), the site must provide the BC IRB with evidence that they support the research being conducted at their location. If the site has an IRB, you should consult with that IRB to determine whether they require IRB approval from their institution in addition to IRB approval through BC. If they do not have an IRB, please provide a site permission letter. Site permission letters should be written on the letterhead of the institution and signed by a Principal or Administrator.

A. Are you conducting research at a site? ○ Yes ◉ No

IX. Acknowledgement

SUBMISSION OF A PROPOSAL TO THE BC IRB REQUIRES THAT THE PRINCIPAL INVESTIGATOR (AND MENTOR IF THE PI IS A STUDENT OR FELLOW) SIGN THIS PAGE AND READ COMPLETELY THE DEFINITION OF "SCIENTIFIC MISCONDUCT" AND ANSWER ALL "CONFLICT OF INTEREST" QUESTION GIVEN BELOW.

A. Scientific Misconduct

"Scientific Misconduct" shall be considered to include:

1. Fabrication, falsification, plagiarism or other unaccepted practices in proposing, carrying out or reporting results from research;
2. Material failure to comply with Federal requirements for the protection of human participants, researchers and/or the Public;
3. Failure to meet other material legal requirements governing research;
4. Failure to comply with established standards regarding author names on publications;
5. Failure to adhere to issues of confidentiality as provided in the participant consent form, the study protocol, and as outlined in the Code of Federal Regulations **(45 CFR 46)**.

Conflict of Interest

1. Are you or any member of your immediate family (spouse or domestic partner and/or dependent children) an officer, director, partner, trustee, Employee, advisory board member, or agent of (a) the external organization funding this Sponsored Project or (b) any external organization from which goods and services will be obtained under this Sponsored Project (including those to which you may be subcontracting a portion of the project work), (c) any external organization whose financial condition could benefit from the results of this Sponsored Project, or (d) any external organization having business dealings in an area related to the work under this Sponsored Project?

○ Yes (if so, describe in detail the nature and extent of the association on an attached sheet).
◉ No

2. Publicly-Traded Entities: Have you or any member of your immediate family derived income within the past year of $5,000 or more in a publicly-traded entity, or in the past year have you or any member of your immediate family owned equity interests in a public-traded interest, the fair market value of the equity being $5,000 or more?

○ Yes (If any of the following pertain, provide a full description on a separate sheet):

(a) The entity is co-funding this Sponsored Project;

(b) The income or equity is related the your university responsibilities (e.g. research, teaching, and service);

(c) The entity may provide goods and services under this Sponsored Project (including those to which you may be subcontracting a portion of the project work);

(d) The entity's financial condition may benefit from the results of this Sponsored Project; or

(e) The entity has business dealings in an area related to the work under this Sponsored Project?

◉ No

3. Non-Publicly Traded (i.e. Privately Held) Entities: Have you or any member of your immediate family derived income within the past year of $5,000 or more in a non- publicly traded entity, or in the past year have you or any member of your immediate family owned any equity interests in a non-publicly traded entity?

○ Yes (If any of the following pertain, provide a full description on a separate sheet):

(a) The entity is co-funding this Sponsored Project;

(b) The income or equity is related the your university responsibilities (e.g. research, teaching, and service);

(c) The entity may provide goods and services under this Sponsored Project (including those to which you may be subcontracting a portion of the project work);

(d) The entity's financial condition may benefit from the results of this Sponsored Project; or

(e) The entity has business dealings in an area related to the work under this Sponsored Project?

◉ No

Research Staff

Added Personnel	Staff Type	EPPN	Date of IRB Training Certificate
Hodges, James	Research Assistant	hodgesjb	05/03/20
Email			
hodgesjb@bc.edu			

Added Personnel	Staff Type	EPPN	Date of IRB Training Certificate
LESTER MCSWEENEY, MAURA R	Research Assistant	lestermc	01/26/21
Email			
MAURA.LESTERMCSWEENEY@BC.EDU			

Added Personnel	Staff Type	EPPN	Date of IRB Training Certificate
Familiar-Bolanos, Marcela	Research Assistant	familiam	02/04/21
Email			
marcela.familiar-bolanos@bc.edu			

Added Personnel	Staff Type	EPPN	Date of IRB Training Certificate
Palacios Pizarro, Estefania	Research Assistant	EPalaciosPizarro	05/31/21
Email			
ecpalacios@uc.cl			

Added Personnel	Staff Type	EPPN	Date of IRB Training Certificate
Mendez Campos, Barbara	Research Assistant	BMendezCampos	12/04/19
Email			
mendezba@bc.edu			

SIGNATURE OF PRINCIPAL INVESTIGATOR

The undersigned accept(s) responsibility for the study, including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the ethical principles of your discipline, the Common Rule and Boston College policies regarding protection of the rights and welfare of human participants participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies.

Signed by Christopher Salas-Wright on Oct 07, 2021

SIGNATURE OF FACULTY RESEARCH SUPERVISOR- REQUIRED FOR STUDENT RESEARCH
By signing this form, I certify that: