

INDEPENDENT COMMERCIAL IRB

NEW PROJECT – NON-EXEMPT STUDY
IRB APPLICATION FORM

NOT FOR USE IF REQUESTING EXEMPTION OF FULL PROJECT

Name of Project (Use title submitted to funding source): Safe Keeping		
Principal Investigator (PI): Melinda Hostler	Email: MHostler@gmail.com	Phone: 919.555.5555
Organization: Healthy Families Institute		
Address: 115 Central Drive Durham, NC 27715		
Is there an IRB Authorization Agreement in place for this project (i.e., Independent Commercial IRB is reviewing the work of another organization)?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, indicate other organization(s) involved (Be sure to include the activities of the other organization[s] in this submission form and submit signed IRB Authorization Agreement with package.):		
Are you seeking approval in principle (or approval for your preliminary plan) for JIT (Just-In-Time) purposes?		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Does this project involve potential vulnerable populations?		
<input checked="" type="checkbox"/> Children	<input type="checkbox"/> Persons with mental disabilities	
<input type="checkbox"/> Prisoners	<input type="checkbox"/> Economically or educationally disadvantaged persons	
<input type="checkbox"/> Pregnant women	<input type="checkbox"/> Other:	

1 SUMMARY — Provide a brief summary that includes:

- the nature of the research to be conducted;
- the study aims; and
- study components (a component consists of a set of subjects and data collection activities for those subjects).

If this project is a collaborative, indicate collaborators and clarify your organization's role in the project.

Date of present submission: December 2, 2019

Summary of the Research:

The purpose of the study is to collect data from students enrolled in the Safe Keeping program implemented within two high schools in Durham, N.C. Safe Keeping is a voluntary program aimed at changing social norms regarding sexual activity and teaching youth to avoid pre-marital sex and other risk behaviors. Data collected about the Safe Keeping program will be used to assess student characteristics, behaviors, strengths, experiences, perceptions about program effects, decision-making, and experiences in the program. These data will be used for making federal and local program improvements and may affect decision-making about future program funding and expansion, community service delivery collaboration, and the field of sexual risk avoidance education.

Specific Aims: The aim is to collect performance measures entry and exit survey data from students participating in the Safe Keeping program. The aims of the Safe Keeping program are to:

- Adapt the evidence-based Promoting Health Among Teens! (PHAT!) Abstinence-Only Program to address Sexual Risk Avoidance Education (SRAE) legislative requirements (e.g., self-regulation, success sequencing to avoid poverty, alcohol and other drug use);
- Hire, train, and supervise facilitators to deliver the adapted eight-session program; and
- Deliver the adapted program (Safe Keeping) to all students enrolled in health classes in two Durham high schools.

Study Components:

This study involves collecting performance measures data from students using entry and exit surveys. The surveys will collect information about youth characteristics, behaviors, perceptions of program effects, and program experiences. A separate study component to collect additional performance measures and implementation fidelity data from sub-awardees and facilitators has been discussed with Independent Commercial IRB, and we will submit a separate request for IRB exemption for that component.

Study Collaborators: Collaborators include the Westbrook and Eastbrook High Schools in Durham, N.C., and the Youth Are our Future (YAF) nonprofit community-based organization (a sub-awardee to the Healthy Families Institute) that is coordinating the Safe Keeping program. Healthy Families Institute works with YAF to adapt the program, oversees YAF's performance, and collects performance measures data from youth, sub-awardees, and facilitators for reporting to the funder.

2 SUBJECTS — Describe the proposed human subjects including:

- the number to be recruited and their characteristics;
- how they will be contacted and selected for participation; and
- the local research context.

If your project involves more than one group of subjects, describe each group as a separate component.

- If you are obtaining existing data, describe the sources and the types of data they contain, including level of sensitivity.

Healthy Families Institute and YAF staff will seek approval from the school district superintendent to carry out the program by replacing eight weeks of health class with the Safe Keeping program and collect data in two schools (see **Appendix A** for letter to superintendent). We will then approach the two high schools to ask principals for their participation (see **Appendix B** for school MOU). Principals who agree to participate will receive a \$200 donation to the PTA. Principals will be provided with a summary report of findings with data reported at the aggregate level, but no information about individual student responses will be shared in the report.

We will recruit approximately 500 youth (250 enrolled in Westbrook High School and 250 enrolled in Eastbrook High School) in Durham, N.C. This includes all students in grades 9, 10, and 11 who are enrolled in health class at the two schools (about eight classes of 30 students per school). Males and females will be included in the same class and students will be of various races and ethnicities. Only students who speak and read English will be included due to the lack of translation materials. Students with intellectual disabilities will be excluded to ensure students completing the survey have the reading and comprehension levels needed to understand the items.

Letters from the health teacher will be sent home to parents describing the entry and exit surveys and requesting active consent (see **Appendices C and D** for letter to parents/guardians and parent consent form). Students whose parents/guardians return the signed letters indicating that the parent/guardian has given permission will be asked during health class to assent to participate in data collection (see **Appendix E** for youth assent form).

The local research context is two high schools with the highest proportion of students receiving free or reduced lunch assistance in the county. The high schools serve a suburban area that is 33% white, 33% African American, 33% Latino, and 1% other (multiracial, Asian, Native American, etc.).

3 PROCEDURES — For each component, explain:

- what will be expected of participants;
- the procedures for obtaining informed consent; and
- how data will be collected and maintained.

Students will be asked to complete an eight-minute anonymous paper and pencil entry survey before the Safe Keeping program begins and a 16-minute anonymous paper and pencil exit survey after the Safe Keeping program ends (see **Appendices F and G** for entry and exit survey questionnaires). Survey data will be collected from students in the health classroom in the week prior to program implementation and the week after program implementation (the program lasts for eight weeks). Students will complete each survey in the same classroom that they take the health class.

Letters from the health teacher will be sent home to parents describing the entry and exit surveys and requesting active consent (see **Appendices C and D** for letter to parents/guardians and parent consent form). Only students whose parents/guardians return the signed letters indicating that the parent/guardian has given permission will be allowed to participate in the surveys. A copy of the entry and exit survey questionnaires will be kept at the principal's office for any parent who would like to view the questionnaires prior to providing consent. A presentation of the Safe Keeping program and the survey will be made at a PTA meeting at each high school prior to the program starting. The YAF staff who will be implementing the program and collecting the data will be

present at the PTA meetings to describe the program and data collection efforts. Health teachers will be trained to distribute and collect the forms from parents/guardians and will receive a pizza party and a \$25 gift card for classroom supplies for each class that returns at least 80% of consent forms signed by parents (whether the parent/guardian has indicated yes or no to participation). Health teachers also will be educated about the purpose of the project and have a copy of the questionnaires in case parents contact them regarding questions on the survey purpose and topics. Students will receive \$1, a wristband, a free cookie in the cafeteria, or an item at the school store (like a pencil) for returning signed consent forms (whether the parent has indicated yes or no to participation). All students in the health class with signed consent from parents, and who themselves assent to participation in performance measures entry and exist survey data collection (see **Appendix E** for youth assent form), will be able to participate in the surveys.

Surveys will be distributed by a staff person from YAF. The data collector will be a different person than the one who implemented the program. The data collector will be trained on data collection procedures to ensure privacy, how to respond to questions about the survey in a consistent manner, and how to identify and respond to distress and disclosures of child abuse or imminent danger (see **Appendix H** for distress and disclosures protocol). The data collector will discuss the materials in unsealed manila envelopes to be distributed (see **Appendix I** for script). The envelopes contain the entry survey, an assent form, a blank sheet of paper, and a sheet of paper that lists referral services including the school guidance counselors for students who would like to talk with someone about any of the issues on the survey or any distress that arises while completing the survey (see **Appendix J** for the referral list). The data collector will emphasize that the surveys are voluntary and students can stop anytime or skip any question. Students will be informed of the purpose and types of questions on the survey; how they were selected; procedures for confidentiality and privacy; and information on how the data will be stored, analyzed, and disseminated.

Students will be seated at desks in the health classroom with as much space between students as possible for privacy. Students will be provided with a blank sheet of paper to cover the survey answers as they move through the survey to increase privacy. No identifying information will be on the survey or envelope. Students who are absent for the entry survey and begin receiving Safe Keeping program content will not be asked to take the entry survey. The survey will collect sensitive information including sexual orientation; living situation (including foster care, detention center, homeless); use of alcohol, tobacco, or other drugs; sexual activity; incidence of pregnancy or STI; and perceptions of the Safe Keeping program's effects on their sexual activity. Surveys will not be linked from entry to exit. Thus, it is a cross-sectional, not a longitudinal, study design. The survey will not be read out loud to prevent students from looking at what responses their peers are marking. Each student will be responsible for reading and answering questions on their own; however, they may raise their hand to ask about an item on the survey. When they are finished, students will put the assent form and questionnaire back into the envelope and seal the envelope. This process will occur twice—once prior to program implementation (entry survey) and once after the eight-week program (exit survey). Exit survey questionnaires will be provided only to students with parent consent and assent at entry survey. These students will be reminded that their parents consented, and they assented, to two waves of data collection (see **Appendix K** for script). In addition, parent consent and youth assent procedures (described earlier) will be followed prior to exit survey for students not present for the entry survey (see **Appendices L and M** for parent consent and youth assent for exit survey only). Students without parent consent or who did not assent will be given a word search puzzle or allowed to read or complete homework during survey administration.

The sealed envelopes will be taken back to YAF by the data collector. The evaluation staff will enter the data into an Excel spreadsheet. No personally identifiable information will be included in the Excel file. The data files will include a code for classroom and school so that group level changes over time can be identified. At both YAF and Healthy Families Institute, the data file will be on a secure computer server and the computer will be password protected. Only project staff who sign a confidentiality agreement will have access to the data (see **Appendix N** for the staff confidentiality agreement). Electronic files will be transmitted via encrypted CD and hand delivered to Healthy Families Institute. The password will be transmitted separately (via e-mail or voice mail message). Hard copies of the completed questionnaires will be stored in a locked file cabinet at the YAF office. Completed parent consent forms, youth assent forms, and rosters of youth with parent consent and who assented will be stored in a

separate locked file cabinet and/or on a separate secure computer server. One year after the survey completion, identifying information from the consent and assent forms and class rosters will be deleted. Hard copies of questionnaires will be shredded and the computer files will be deleted three years after the 2020-2021 school year data collection period (by 06-10-2024).

All findings will be presented at the group level and no information about the individual students who participated in the data collection effort will be revealed.

We will seek permission to share these data with the federal government (as a requirement of our grant) separately.

4 RISKS — For each component, describe foreseeable physical, psychological, and/or social risks to the subjects.

There are minimal risks involved in this data collection effort.

It is possible, despite safeguards discussed below, that a student's response to a sensitive question could be seen by another student or somehow revealed. Items on the questionnaire address sensitive subjects, including sexual orientation; living situation (including foster care, detention center, homeless); use of alcohol, tobacco, or other drugs; sexual activity; incidence of pregnancy or STI; and perceptions of the program's effects on sexual activity. If responses were revealed, students could experience stigma, embarrassment, and/or legal consequences for underage or illegal substance use.

There are also minimal risks of a student becoming distressed by topics included in the survey. Data collectors will be trained in identifying and responding to distress (see below).

5 SAFEGUARDS — For each non-exempt component, explain the procedures to be used to minimize each of the potential risks listed in Section 4. Describe procedures for:

- protecting the participants' privacy;
- maintaining confidentiality of the data; and
- monitoring staff compliance with the IRB-approved protocol.

Several safeguards will be in place to minimize risk.

To ensure privacy, the data collector will take care to place students around the room such that there is as much space as possible between students. Students also will be provided a blank sheet of paper to cover their responses as they complete the survey. There will be no identifying or personal information on the survey. When complete, the anonymous survey will be placed in a sealed envelope with no identifying information on it. Data will not be linked from entry to exit, so there is little opportunity for someone to determine the identity of the respondent. The data collectors will be trained in human subjects protection and confidentiality. They also will be required to sign a data confidentiality agreement. No personally identifiable information will be included in data files about survey responses. At both YAF and Healthy Families Institute, the data file will be on a secure computer server and the computer will be password protected. Only project staff who sign a confidentiality agreement will have access to the data. Electronic files will be transmitted via encrypted CD and hand delivered to Healthy Families Institute. The password will be transmitted separately (via email or voice mail message). Hard copies of the completed questionnaires will be stored in a locked file cabinet at the YAF office. Completed parent consent forms, youth assent forms, and rosters of youth with parent consent and who assented will be stored in a separate locked file cabinet and/or on a separate secure computer server. One year after the survey completion, identifying information will be deleted. Hard copies of questionnaires will be shredded and the computer files will be deleted at the end of the grant (09-30-2021). All findings will be presented at the group level and no information about the

individual students who participated in the data collection effort will be revealed. Data analysis will be done at the aggregate level.

To minimize risk of distress, parents will provide active consent and students will sign assent forms before data collection. Parents and students who are not comfortable with topics addressed in the survey may decline to participate with no consequences. Students will be told they can skip any question or discontinue survey participation at any time. The data collector will be trained in identifying and responding to distress and will have referral information on hand. The data collector will also be trained in responding to disclosures of suspected child abuse or imminent harm and will follow legal requirements and reporting protocols if such situations occur. Prior to conducting the survey, YAF will consult with the principals and guidance counselors at both high schools to get the names of the guidance counselors and other referral services that the schools use if they need to provide families or students with the names of social or behavioral services to address emotional or behavioral problems. These resources will be provided on a sheet of paper included in the students' survey packet. Guidance counselors will also be alerted on the days of the survey administration in case any students seek their attention.

6 BENEFITS — For each non-exempt component, describe benefits to be derived from the proposed research for the participants and/or for society.

Potential Benefits of the Proposed Research to Human Subjects and Others

There are no individual benefits of participation in the entry and exit surveys.

Importance of the Knowledge to be Gained

Data collected about the Safe Keeping program will be used to assess student characteristics, behaviors, strengths, experiences, perceptions about program effects, decision-making, and experiences in the program. These data will be useful for federal and local program improvements, decision-making about future program funding and expansion, community service delivery collaboration, and for the field of sexual risk avoidance education.

Be sure to include all relevant appendices (recruitment fliers, instruments, consent forms, consent scripts, etc.) in your submission package

Appendices:

- Appendix A: Letter to superintendent
- Appendix B: School MOU
- Appendix C: Letter to parents/guardians
- Appendix D: Parent consent form
- Appendix E: Youth assent form
- Appendix F: Entry survey questionnaire
- Appendix G: Exit survey questionnaire
- Appendix H: Distress and disclosures protocol
- Appendix I: First survey administration script
- Appendix J: Referral list
- Appendix K: Script for second survey administration
- Appendix L: Parent consent form for exit survey only
- Appendix M: Youth assent form for exit survey only
- Appendix N: Staff confidentiality agreement