A. COVER PAGE

Project Title: Youth Empowerment Solutions:Ã□Â□Ã□Â Engaging Youth for Anti-Racism And Cultural Equity (YES-ERACE)	
Grant Number: 5R01MD015024-03	**Project/Grant Period:** 09/24/2020 - 03/31/2025
Reporting Period: 04/01/2021 - 03/31/2022	**Requested Budget Period:** 04/01/2022 - 03/31/2023
Report Term Frequency: Annual	**Date Submitted:** 02/02/2022
Program Director/Principal Investigator Information: MARC A ZIMMERMAN , PHD BS MS **Phone Number:** 7346470224 **Email:** marcz@umich.edu	**Recipient Organization:** UNIVERSITY OF MICHIGAN AT ANN ARBOR 3003 SOUTH STATE STREET 1st Floor Wolverine Tower ANN ARBOR, MI 481091276 **DUNS:** 073133571 **EIN:** 1386006309A1 **RECIPIENT ID:**
Change of Contact PD/PI: NA	
Administrative Official: TRACEY LARKIN 3003 South State Street Ann Arbor, MI 48109 **Phone number:** 734-764-7237 **Email:** larkint@umich.edu	**Signing Official:** TRACEY LARKIN 3003 South State Street Ann Arbor, MI 48109 **Phone number:** 734-764-7237 **Email:** larkint@umich.edu
Human Subjects: Yes **HS Exempt:** NA **Exemption Number:** **Phase III Clinical Trial:** NA	**Vertebrate Animals:** No
hESC: No	**Inventions/Patents:** No

B. ACCOMPLISHMENTS

B.1 WHAT ARE THE MAJOR GOALS OF THE PROJECT?

We will adapt our YES curriculum to empower youth from diverse backgrounds to address racism and racial discrimination as a way to reduce violent behavior. YES for Engaging youth for anti-Racism And Cultural Equity (YES-ERACE) will focus on middle school students because this is a developmental period when racial identity development becomes a central developmental task29 awareness of racism develops,30 their own ideas about interpersonal relationships are formative,31 and when bullying behavior is at its peak.32 Empowering youth to address racial prejudice and racist behaviors may, in part, contribute to reductions in violent behaviors. We will work with an Advisory Board involved in undoing racism work to integrate the Teaching Tolerance (TT)33 curriculum from the Southern Poverty Law Center, one of the oldest civil rights organizations in the U.S., into the existing YES curriculum. The YES curriculum has many natural places to integrate TT modules to insure the theme of undoing racism is present throughout the new YES-ERACE curriculum. A unique feature of YES-ERACE is that youth will design and implement projects with a focus on undoing racism.

Our study will include two phases: 1) adapting YES and 2) testing YES-ERACE effects. Phase 1 will include piloting and evaluating curriculum revisions through testing new modules and obtaining feedback from youth and teachers. Phase 2 will test the effects of YES-ERACE using a group-randomized trial in non-academic summer programs across 6 middle schools. YES-ERACE projects will be youth-driven. We will examine the effects of the curriculum on individual youths' sense of empowerment, racism attitudes, and violent behavior. Finally, we will examine dose-response and sustainability of YES-ERACE effects. Our Specific Aims are:

AIM 1: adapt the YES curriculum to integrate several modules from the TT curriculum and study the adaptation and implementation process for the new curriculum for racially diverse groups of middle school students;

AIM 2: test the efficacy of the YES-ERACE curriculum in a randomized design on empowered outcomes which will mediate the effects of YES-ERACE on perpetration of racist attitudes and behavior;

AIM 3: investigate if empowered outcomes are the mechanism by which the YES-ERACE curriculum reduces racist behavior and aggressive and violent behavior (especially those motivated by racism) over time.

AIM 4: study the effects of dose-response over time on the outcomes from AIMS 2 and 3.

We expect findings from this study will provide evidence for a racial tolerance program based on empowerment that will reduce discrimination and racially motivated aggression in racially diverse middle school youth.

B.1.a Have the major goals changed since the initial competing award or previous report?

No

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

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B.3 COMPETITIVE REVISIONS/ADMINISTRATIVE SUPPLEMENTS

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

No

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

NOTHING TO REPORT

B.5 HOW HAVE THE RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

NOTHING TO REPORT

B.6 WHAT DO YOU PLAN TO DO DURING THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

We have identified three middle schools to implement the revised YES-IDEAS curriculum as an 8-week after-school program this Spring (2022), beginning in April. While we initially intended the new YES-IDEAS curriculum to be implemented as a summer program, following the first pilot the schools requested we change our approach to make it an after-school program instead. This was due to limited enrollment numbers in summer school (exacerbated by COVID-19), and the need for academic remediation among most youth enrolled in summer school. Given YES was originally developed as an after-school program, this was not a significant issue because the modifications needed to pivot from summer to after-school were minimal. We also planned to implement the after-school program in January 2022, but our school partners suggested we postpone due to the COVID surge in Genesee County and the fact that schools may be open and closed during this quarter.

We will conduct a process evaluation of the second revision of the YES-IDEAS curriculum this Spring. The process evaluation will include information from student surveys, as well as qualitative interviews with students and teachers. With information from the process evaluation, we will make further modifications to the curriculum over the summer (2022). We are working with the schools to implement YES as an after school program at 6 schools in Genesee County in Fall 2022. By implementing the program this Spring (2022), and again this Fall (2022) we expect to increase our N and achieve our overall recruitment goals and evaluate the efficacy of the YES program on youth empowerment (aims 2-4).

Aim 1: Adapting the YES Curriculum

We conducted the first round of curriculum revisions in Spring 2021. We used the ADAPT-ITT (*Assessment, Decision, Adaptation, Production, Topical experts, Integration, Training, and Testing*) framework to guide the adaptation of YES, expanding the scope of the intervention to address racial/ethnic discrimination. We assembled an Advisory Board of local leaders involved in undoing racism work and *Teaching Tolerance*. Our Advisory Board included: **James Yake**, Genesee Intermediate School District (GISD) Superintendent; **Aimee Phillips,** director of GISD's 21st Century After School Programs; **Sue Peters**, Vice President of Community Impact, Community Foundation of Greater Flint and **Jessyca Matthews**, English teacher at Carman-Ainsworth High School in GISD with expertise in Teaching Tolerance. We also consulted with **Dr. Enrique Neblett,** who at the beginning of the project joined the faculty at the University of Michigan in our Departments.

The initial curriculum adaptation included the following steps:

1) We assessed potential barriers to implementation through interviews with school personnel to develop a comprehensive understanding of resources and issues regarding the promotion of diversity, equity and inclusion (DEI) among middle school students.

2) We worked with our Advisory Board to obtain comments on our revisions and to apply this information for informing decisions about YES-ERACE adaptations.

3) We produced a detailed manual and all related instructional materials (student handouts, supplies lists) for the new YES-ERACE curriculum.

4) We developed our evaluation materials (e.g., questionnaire, implementation fidelity measures) and training protocol during this stage of adaptation, in consultation with our topical experts.

5) We conducted a pilot test of the adapted curriculum (Summer 2021) with middle school students and teachers participating in one summer school program in Genesee county.

6) We asked youth and teachers from the pilot testing to participate in small group discussions about what they liked and did not like about the program.

After the initial curriculum adaptation and pilot testing (Spring-Summer, 2021), we obtained student and teacher feedback and along with discussion with staff who implemented the curriculum and we made further revisions to the curriculum in Fall 2021. Based on the feedback from students and teachers, and discussions with implementing staff and school administrators, we have decided to expand the lessons to include anti-racism as well as other discriminatory practices focused on LGBTQ and physical differences and disability. Specifically:

1) We modified lesson 1.2 on terminology. Feedback from students and teachers indicated that there were too many terms, and that students had a difficult time retaining the information after the lesson. We reduced the number of terms in the initial terminology lesson, provided more examples and scaffolding (i.e., videos and additional activities), and incorporated terminology reviews throughout the program to reiterate the key concepts. We eliminated the following terms from lesson 1.2: Color Evasive, Colorism, Cultural Appropriation, Code Switching, White Supremacy, and Ableism. These terms are now covered in different lessons later in the curriculum (i.e., in lesson 1.6 on Community and Media Stereotypes and lesson 3.2 on Race and Poverty). We added the following terms to the lesson: LGBTQ and Solidarity.

2) We include a new lesson on LBGTQ appreciation (lesson 1.8), given the history of LBGTQ discrimination and activism in the U.S. This lesson connects to what students learn in the program about racial/ethnic discrimination, and provides additional context for understanding social justice movements in the United States. Relatedly, we added an activity and discussion addressing physical differences and disability.

4) We modified lesson 1.7 (formerly “teamwork and social change movements”) to focus on **Solidarity**. We define solidarity, ask students to think of examples of solidarity in their own lives, and demonstrate (through group discussion and video clips) how solidarity is the foundation of successful social change movements. We added a game to demonstrate the key concepts of solidarity (i.e., we can accomplish more together than individually.)

5) We adapted the “cycle of poverty” lessons (3.1 and 3.2), given feedback from students and the teachers that some of the content and activities were beyond students’ academic level. We identified new age-appropriate resources from *Learning for Justice* (formerly known as *Teaching Tolerance*) and incorporated new activities and video examples to teach students about how poverty affects educational and employment outcomes. The lessons culminate in an activity entitled “President for a Day”, where students decide how they would allocate resources to address societal inequities if they were the president for a day.

6) We adapted the survey questionnaire based on feedback that it was too long and some of the items were beyond students’ reading level. We modified the items to the appropriate reading level and reduced the number of questions. All items in the questionnaire assess constructs presented in the conceptual model, which has not changed.

7) We have obtained University IRB approval for all these adaptations. Given our expanded focus, we have renamed the program YES-IDEAS (Youth Empowerment Solutions for Inclusion, Diversity, Equity, Appreciation, Solidarity).

AIM 2: YES-ERACE intervention effect on Empowerment.

We conducted a pilot test of the YES-ERACE curriculum in Summer 2021 to examine the effect of the YES-ERACE intervention on empowerment outcomes. The number of participants, however, was too small to conduct analyses examining the intervention effects. Our low participation rate was due to COVID-19 challenges this summer. See section B-6 for our plans for addressing Aims 2-4 in the next reporting period.

Aim 3: To examine the mediational model from YES-ERACE to violent behavior.
Nothing to report at this time, but we are moving forward to eventually achieve this aim.

AIM 4: YES-ERACE dose-response effects and sustainability over time.
Nothing to report at this time, but we are moving forward to eventually achieve this aim.

C. PRODUCTS

C.1 PUBLICATIONS

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

No

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S)

Category	Explanation
Educational aids or curricula , Research Material	https://yes.sph.umich.edu/ This website has been used to disseminate information about the YES program, including general program information, descriptions of YES curriculum, and results from prior evaluations.

C.3 TECHNOLOGIES OR TECHNIQUES

NOTHING TO REPORT

C.4 INVENTIONS, PATENT APPLICATIONS, AND/OR LICENSES

Have inventions, patent applications and/or licenses resulted from the award during the reporting period? No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization?

C.5 OTHER PRODUCTS AND RESOURCE SHARING

NOTHING TO REPORT

D. PARTICIPANTS

D.1 WHAT INDIVIDUALS HAVE WORKED ON THE PROJECT?

Commons ID	S/K	Name	Degree(s)	Role	Cal	Aca	Sum	Foreign Org	Country	SS
eRA Commons User Name	Y	Zimmerman, Marc A	BS,MS,PHD	PD/PI	EFFORT					NA
	N	North, Elizabeth Anne	PhD	Postdoctoral Scholar, Fellow, or Other Postdoctoral Position						NA
	N	Agi, Abunya	PHD	Post Doctoral Fellow (era commons user id in process)						NA
	N	Wyatt, Rachel	BA, MS	Statistician						NA
	N	Redacted by agreement		Undergraduate student; ERA commons user ID in progress						NA
	N	Franzen, Susan		Research Specialist						NA
	N	Grodzinski, Alison		Research Specialist						NA
	N	Redacted by agreement		Graduate student; ERA commons user ID in progress						NA
	N	Stewart, Ardele		Research Secretary						NA
	N	Hutchison, Pete		Consultant						NA
	N	Neblett, Enrique	PHD	Faculty						NA
	N	Alberts, Joseph		Web Administrator						NA

Glossary of acronyms:
S/K - Senior/Key
DOB - Date of Birth
Cal - Person Months (Calendar)
Aca - Person Months (Academic)
Sum - Person Months (Summer)
Foreign Org - Foreign Organization Affiliation
SS - Supplement Support
RE - Reentry Supplement
DI - Diversity Supplement
OT - Other
NA - Not Applicable

D.2 PERSONNEL UPDATES

D.2.a Level of Effort

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in the level

of effort below the minimum amount of effort required by the Notice of Award? No
D.2.b New Senior/Key Personnel Are there, or will there be, new senior/key personnel? No
D.2.c Changes in Other Support Has there been a change in the active other support of senior/key personnel since the last reporting period? No
D.2.d New Other Significant Contributors Are there, or will there be, new other significant contributors? No
D.2.e Multi-PI (MPI) Leadership Plan Will there be a change in the MPI Leadership Plan for the next budget period? No

E. IMPACT

E.1 WHAT IS THE IMPACT ON THE DEVELOPMENT OF HUMAN RESOURCES? Not Applicable
E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE? NOTHING TO REPORT
E.3 WHAT IS THE IMPACT ON TECHNOLOGY TRANSFER? Not Applicable
E.4 WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)? NOTHING TO REPORT

F. CHANGES

F.1 CHANGES IN APPROACH AND REASONS FOR CHANGE

Not Applicable

F.2 ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

The main challenge this reporting period has been reaching our enrollment numbers, which were lower than expected due to the COVID-19 pandemic. In our Summer 2021 pilot, five students participated in YES as part of their summer school program. We consulted with our advisory board and GISD partners, and decided to implement the program going forward as an after-school rather than summer program. Offering YES as an after-school program will provide greater opportunities to increase our enrollment numbers, given that there are four 8-week blocks of after-school programming offered at GISD each school year.

We had planned to implement YES as an after-school program beginning in January 2022, but the spread of the Omicron variant led to staffing shortages and scheduling difficulties across the district and the schools requested we postpone until later in the Spring.

We will deliver the program at 3 GISD middle schools starting in April 2022, and again at 6 schools beginning in September 2022. We also anticipate a no-cost extension year in order to boost our enrollment numbers.

F.3 SIGNIFICANT CHANGES TO HUMAN SUBJECTS, VERTEBRATE ANIMALS, BIOHAZARDS, AND/OR SELECT AGENTS

F.3.a Human Subject

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F.3.b Vertebrate Animals

No Change

F.3.c Biohazards

No Change

F.3.d Select Agents

No Change

F.3.a (Protocol Change.pdf)

Description of Protocol Change

Our process for obtaining parental consent has changed. Prior to this, parents would return a signed consent form indicating if they wanted their child to participate or not. We have now received approval from the school district and the IRB for a passive consent procedure. This means that all students who enroll in the YES program at GISD will participate in the evaluation, unless parents notify the study team that they do NOT want their child to participate. Our approved IRB protocol outlines these changes, and is attached to this report.

eRESEARCH | REGULATORY MANAGEMENT

Date: Monday, January 31, 2022 11:18:12 PM Print Close

View: 01. General Study Information
Section: 01. General Study Information

01. General Study Information

The forms menu on the left displays all sections and pages of the application. Pages in **bold** are required. Pages in *italics* may not apply to your project. Use the "Continue" button to advance through the smartform, as it will only display the sections that must be completed.

All questions marked with a red asterisk (*) are required. Questions without a red asterisk may or may not be required, depending on their relevance to the study.

1.1* Study Title:

YES IDEAS

1.1.1 Full Study Title:

YES for Engaging Youth for anti-Racism And Cultural Equity (YES-ERACE)

Ame00117777
Changed study title
Youth Empowerment Solutions for Inclusion, Diversity, Equity, Appreciation, and Solidarity (YES IDEAS)

1.1.2 If there are other U-M studies related to this project, enter the eResearch ID number (HUM#) or IRBMED Legacy study number. Examples of related projects include, but are not limited to:

- Projects funded under the same grant
- IRBMED Legacy study being migrated into eResearch
- Previously approved Umbrella applications (such as Center Grants or approvals for release of funding)
- Previously approved projects for which this is a follow up study

HUM00173030 (Umbrella)

1.1.3* Does this application include the study of COVID-19?

For example:

- **testing or studying the COVID-19 virus,**
- **exploring treatment options,**
- **studying the impact of the COVID-19 pandemic (This could included epidemiological, social, behavioral, or educational research).**

Note: Answer "Yes" only if this project includes the study of COVID-19. Inclusion of study procedures solely intended to allow the research to be conducted under pandemic constraints, such as remote interactions with subjects, remote consenting, or at-home drug delivery are not considered the study of COVID-19.

○ Yes ● **No**

1.2* Principal Investigator:

Marc Zimmerman
Note: If the user is not in the system, you may Create A New User Account...

1.3 Study Team Members:

Study Team Member	Study Team Role	Appointment Dept	Appointment Selection Complete?	Student	Friend Account	COI Review Required	Edit Rights	Accepted Role?	PEERRS Human Subjects?
Marc Zimmerman	PI	Hlth Behavior & Hlth Ed Dept	Yes	no	No	no	yes	N/A	yes
Riana Anderson	Co-Investigator	Hlth Behavior & Hlth Ed Dept	Yes	no	No	no	no	Yes	yes
Hsing-Fang Hsieh	Co-Investigator	Hlth Behavior & Hlth Ed Dept	Yes	no	No	no	no	Yes	yes
Kelley Kidwell	Co-Investigator	Biostatistics Department	Yes	no	No	no	no	Yes	yes

Study Team Member	Study Team Role	Appointment Dept	Appointment Selection Complete?	Student	Friend Account	COI Review Required	Edit Rights	Accepted Role?	PEERRS Human Subjects?
Enrique Neblett	Co-Investigator	Hlth Behavior & Hlth Ed Dept	Yes	no	No	no	no	Yes	yes
Deborah Rivas-Drake	Co-Investigator	LSA Psychology	Yes	no	No	no	no	Yes	yes
Sarah Stoddard	Co-Investigator	School of Nursing	Yes	no	No	no	no	Yes	yes
Susan Franzen	Study Coordinator/Project Manager	Hlth Behavior & Hlth Ed Dept	Yes	no	No	no	yes	Yes	yes
Alison Grodzinski	Study Coordinator/Project Manager	Hlth Behavior & Hlth Ed Dept	Yes	no	No	no	yes	Yes	yes
Elizabeth Messman	Study Coordinator/Project Manager	Hlth Behavior & Hlth Ed Dept	Yes	no	No	no	yes	Yes	yes
Catherine Gong	Research Staff	Hlth Behavior & Hlth Ed Dept	Yes	no	No	no	no	Yes	yes
Redacted by agreement			Yes	yes	No	no	yes	Yes	yes
Karen Weiss	Research Staff	Hlth Behavior & Hlth Ed Dept	Yes	no	No	no	no	Yes	yes
Rachel Wyatt	Research Staff	Hlth Behavior & Hlth Ed Dept	Yes	no	No	no	no	Yes	yes
Joe Alberts	Administrative Staff	Hlth Behavior & Hlth Ed Dept	Yes	no	No		no	N/A	yes
Ardele Stewart	Administrative Staff	Hlth Behavior & Hlth Ed Dept	Yes	no	No		no	N/A	yes

1.8* Project Summary:

Youth violence is a significant public health concern as over 20% report being in a fight, 19% reported bullying someone, and 16% reported weapon carriage.1,2 Violent victimization among youth includes mental health sequelae in addition to the physical injury caused by violent behavior, with the heaviest burden on non-white youth.3–5 Homicide is the leading cause of death for 10-24 year old African Americans and one of the top 3 causes of death for Hispanic and Native American youth.2 Racism, the exercise of power against a racial group defined as inferior, is associated with aggression and violence against racial minority youth.6–12 Researchers have identified two pathways by which racism affects youth violence: 1) as a stressor leading to violence; and 2) as a structural factor resulting in more exposure to community-level risk factors.8,13 Racial prejudice may also increase interracial mistrust, hostility, and violence.14,15 Yet, strategies that integrate undoing racism with violence prevention that also engage youth in change efforts have not been studied systematically.

Our scientific premise is that positive development can be achieved by engaging youth in community improvement activities designed to empower them to avoid risky behaviors.16–18 Building on prior research and guided by our previous studies of empowerment processes,19–23 we developed an afterschool and summer youth violence prevention program for middle-school students called Youth Empowerment Solutions (YES) for Peaceful Communities.24,25 We have described how YES engages youth in assessment of neighborhood assets and liabilities for violence prevention, and designing and implementing neighborhood or school projects that the youth believed would reduce violence.25 We found the YES program reduced violent behavior and increased positive behaviors in a comparison group design26 through the process of empowering youth to think critically about their community, develop plans for change, and implement their plans (i.e., program effects were mediated through empowered outcomes).27,28

We will adapt our YES curriculum to empower youth from diverse backgrounds to address racism and racial discrimination as a way to reduce violent behavior. YES for Engaging youth for anti-Racism And Cultural Equity (YES-ERACE) will focus on middle school students because this is a developmental period when racial identity development becomes a central developmental task29 awareness of racism develops,30 their own ideas about interpersonal relationships are formative,31 and when bullying behavior is at its peak.32 Empowering youth to address racial prejudice and racist behaviors may, in part, contribute to reductions in violent behaviors. We will work with an Advisory Board involved in undoing racism work to integrate the Teaching Tolerance (TT)33 curriculum from the Southern Poverty Law Center, one of the oldest civil rights organizations in the U.S., into the existing YES curriculum. The YES curriculum has many natural places to integrate TT modules to insure the theme of undoing racism is present throughout the new YES-ERACE curriculum. A unique feature of YES-ERACE is that youth will design and implement projects with a focus on undoing racism.

Our study will include two phases: 1) adapting YES and 2) testing YES-ERACE effects. Phase 1 will include piloting and evaluating curriculum revisions through testing new modules and obtaining feedback from youth and teachers. Phase 2 will test the effects of YES-ERACE using a group-randomized trial in non-academic summer programs across 6 middle schools. YES-ERACE projects will be youth-driven. We will examine the effects of the curriculum on individual youths' sense of empowerment, racism attitudes, and violent behavior. Finally, we will examine dose-response and sustainability of YES-ERACE effects. Our Specific Aims are:

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outcomes which will mediate the effects of YES-ERACE on perpetration of racist attitudes and behavior;

AIM 3: investigate if empowered outcomes are the mechanism by which the YES-ERACE curriculum reduces racist behavior and aggressive and violent behavior (especially those motivated by racism) over time.

AIM 4: study the effects of dose-response over time on the outcomes from AIMS 2 and 3.

We expect findings from this study will provide evidence for a racial tolerance program based on empowerment that will reduce discrimination and racially motivated aggression in racially diverse middle school youth.

AME00117777

We changed the name of the project from YES-ERACE to YES-IDEAS (Youth Empowerment Solutions for Inclusion, Diversity, Equity, Appreciation, and Solidarity). We will be conducting the study in an after-school program, rather than a summer program. We made some changes to the survey and have included an updated questionnaire. We have also updated our protocol per Minors Participating in Research guidelines.

1.9* Select the appropriate IRB:

Health Sciences and Behavioral Sciences

1.10* *Estimated* Study Start Date (Not required for IRBMED): (mm/dd/yyyy)

11/1/2020

1.11* *Estimated* Duration of Study:

5 years

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Marc Zimmerman

Preferred email: marcz@umich.edu
Business phone 734-647-0224
Business address: Hlth Behavior & Hlth Educ 3702 SPH I 48109-2029

1.5 Function with respect to project:

PI

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
marcz-bio2013(0.01)	0.01
Professor(0.01)	0.01
Zimmerman CV 2013(0.01)	0.01
Zimmerman CV Jan 2017(0.01)	0.01
Zimmerman CV January 2020(0.01)	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Riana Anderson

Preferred email: rianae@umich.edu
Business phone 734-615-5776
Business address: Health Management & Policy 3822 SPH I; 1415 Washington Heights 48109-2029

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
CV_REA(0.01)	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Hsing-Fang Hsieh

Preferred email: fayenie@umich.edu
Business phone 734-615-5649
Business address: 1415 Washington Heights 3707 SPH I 48109-2029

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
HFH biosketch(0.03)	0.03

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Kelley Kidwell

Preferred email: kidwell@umich.edu
Business phone 734-764-6724
Business address: Biostatistics M4164 SPH II 48109-2029

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
CV(0.01)	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Enrique Neblett

Preferred email: eneblett@umich.edu
Business phone 734-647-5237
Business address: 1415 Washington Heights 2766 SPH I 48109-2029

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
CV 2021(0.01)	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Deborah Rivas-Drake

Preferred email: drivas@umich.edu
Business phone 481042592
Business address: ADVANCE Program 1214 S University Galleria C Flr2 48104-2592

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
DRivasDrake-CV-ALLnumbered.pdf(0.01)	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Sarah Stoddard

Preferred email: sastodda@umich.edu
Business phone 734-647-0327
Business address: School of Nursing 400 N. Ingalls, Rm 4320B 48109-5482

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
Sarah Stoddard CV 2.11.21(0.01)	0.01
Stoddard.CV(0.03)	0.03

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Susan Franzen

Preferred email: sfranzen@umich.edu
Business phone 810-239-3463
Business address: Health Behavior Health Education 400 N Saginaw, Suite 231 48502-0000

1.5 Function with respect to project:

Study Coordinator/Project Manager

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
Susan Franzen CV(0.01)	0.01

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

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- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Alison Grodzinski

Preferred email: alisonrg@umich.edu
Business phone 734-647-0219
Business address: Hlth Behavior & Hlth Ed Dept 3734 SPH I 48109-2029

1.5 Function with respect to project:

Study Coordinator/Project Manager

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
There are no items to display	

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Elizabeth Messman

Preferred email: messman@umich.edu
Business phone 734-763-1989
Business address: HBHE 3700 SPH I 48109-2029

1.5 Function with respect to project:

Study Coordinator/Project Manager

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
Libby North _CV(0.02)	0.02

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

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- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Catherine Gong

Preferred email: gongca@umich.edu
Business phone 734-647-6469
Business address: Hlth Behavior & Hlth Ed Dept 1415 Washington Heights 48109-2029

1.5 Function with respect to project:

Research Staff

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
There are no items to display	

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

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- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Redacted by agreement

Preferred email: Redacted by agreement
Business phone
Business address: Redacted by agreement

1.5 Function with respect to project:

Redacted by agreement

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

Yes

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

Yes

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
There are no items to display	

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

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- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Karen Weiss

Preferred email: kmweiss@umich.edu
Business phone
Business address: 48109

1.5 Function with respect to project:

Research Staff

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
There are no items to display	

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

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- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Rachel Wyatt

Preferred email: wyattra@umich.edu
Business phone 734-647-6469
Business address: Hlth Behavior & Hlth Ed Dept 1415 Washington Heights 48109-2029

1.5 Function with respect to project:

Research Staff

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
There are no items to display	

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Joe Alberts

Preferred email: jra@umich.edu
Business phone
Business address: Health Behavior Health Education 1415 Washington Heights #3700 48109-2029

1.5 Function with respect to project:

Administrative Staff

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
There are no items to display	

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Ardele Stewart

Preferred email: ardy@umich.edu
Business phone 734-763-1989
Business address: Health Behavior Health Education 1415 Washington Hts #3700 48109-2029

1.5 Function with respect to project:

Administrative Staff

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

No

1.7 Include this person on all correspondences regarding this application: (Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)

No

Credentials: Required for PI, Co-Is and Faculty Advisors

Upload or update your CV, resume, or biographical sketch.

Name	Version
There are no items to display	

Conflict of Interest Detail: Required for all roles except Administrative Staff

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

D2 If "Yes" to the question above, provide the name of the outside entity or entities and a brief description of the interest/relationship(s):

View: 01-1. Application Type
Section: 01. General Study Information

01-1. Application Type

1-1.1* Select the appropriate application type.

	Application Type	Description
☑	Human Subjects research **involving interaction or intervention** *(formerly Standard, non-exempt research project - or - Exempt)*	Studies that involve either or both of the following: • Interaction, including communication or interpersonal contact between investigator and subject • Intervention, including both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes Interaction/Intervention studies may also have a "secondary research" component.

Does the research involve any of the following:

a. more than minimal risk to participants?
b. use of drugs or medical devices?
c. target prisoners as research subjects?
d. collection of biospecimens from subjects (including blood, saliva, cheek swabs)?

◯ Yes ● **No**

Some studies involving interaction or intervention with subjects meet the criteria for exemption. Select the category that best describes your research. Detailed questions to verify eligibility are found on the next page. For some studies, you will be able to issue a self-determination.

If none of these categories apply to your research select NONE. Your application will be routed for comprehensive IRB review.

	Exemption Category
◯	**Exemption 1** applies to research that is: • conducted in established **educational settings (typically schools/colleges)**; and • focuses on **normal (accepted) educational practices (e.g. instructional techniques, curricula, classroom management methods** May include use of educational data
◯	**Exemption 2** applies to **most** research that involves collection of information using ONLY one or more of the following: • Surveys (with adults only) • Interviews (with adults only) • focus groups (with adults only) • educational tests • observation of public behavior May involve audio-visual recording but **may not involve an intervention (see exemption 3) or linking to additional personally-identifiable data**.
◯	**Exemption 3** applies to research with **adults only** that involves: • **benign** (not harmful) **behavioral interventions** Examples: ◦ Playing an online game ◦ Solving puzzles under various noise conditions ◦ Playing an economic game ◦ Being exposed to stimuli such as color, light or sound (at safe levels) ◦ Participating in a nutrition education program • **information collected through verbal or written responses** (including methods described in exemption 2 above) • **no physiological data collection** (e.g. blood pressure monitoring, EEG, FitBit, etc.) • **subjects' prospective agreement to participate** in intervention and information collection **May not involve deception** unless subjects are told that they will be misled

	Exemption Category
○	**Exemption 5** applies to **research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads** that are **designed to study, evaluate, improve, or otherwise examine public benefit or service programs**.
○	**Exemption 6 - Taste and food quality evaluation and consumer acceptance studies**
●	**NONE - none of the exemption categories apply to this research.**

☐	**Secondary research** uses of private information or biospecimens	"Secondary research" are studies that involve ONLY re-using private information and/or biospecimens that are collected for some other "primary" or "initial" activity, such as other earlier research studies, a biorepository holding specimens obtained with "broad consent," clinical care, or educational records. Includes Exemption 4 and "not regulated" projects. **Do NOT use this application type for:** • Studies that **also** have an interaction/intervention component, such as primary collection of information or biospecimens for the purposes of the study. (Choose instead "Human subjects research involving **interaction or intervention**.") • Projects involving secondary use of information/biospecimens for **only non-research purposes**, such as QA/QI, case studies on one or two individuals, or use in a class to teach research methods. (Choose instead "Activities **not regulated** as human subjects research.")
☐	Activities **Not Regulated** as human subjects research	Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research (45 CFR 46 or 21 CFR 50/56). **IRB review is required** for the following activities **ONLY** to assess compliance with **HIPAA** or other regulations or institutional policies: • Research on existing data or specimens that have been coded before the researcher receives them, but identifiers still exist. • Research Involving Deceased Individuals Only • Pre-review of Clinical Data Sets Preparatory to Research • Standard Public Health Surveillance or Prevention Activities **IRB review is not required for the following activities**, but researchers may wish complete this brief application to generate a determination letter for funding or publication purposes, or to request IRB review to confirm the "Not Regulated" determination: • Case Studies • Class Activities • Journalism/Documentary Activities • Oral History • Quality Assurance and Quality Improvement Activities • Research on Organizations • Research using Publicly Available Data Sets
☐	Projects **lacking immediate plans for involvement of human subjects**, their data, and/or their specimens	Activities such as training grants, program projects, center grants, or multi-phase studies not involving human subjects until later years. Before release of funding, some agencies may require IRB acknowledgement of the future use of human subjects. These projects are sometimes referred to as "umbrella projects" or "dry applications."
☐	**Single-patient Expanded Access Drug or Biologic (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational drug or biologic, outside of a clinical trial, under a single-patient IND issued by the FDA for a patient faced with a serious or life-threatening disease or condition.

		• Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational drug or biologic is made. • Submission for IRB review and approval is required, prior to use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational agent.** • This includes both one-time use and continuing therapy.
☐	**Single-patient Expanded Access Device Use (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational device, outside of a clinical trial, when this is the only option available for a patient faced with a serious or life-threatening disease or condition. • Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational device is made. • Submission for IRB review and approval is required, prior to device use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational device.** • This includes both one-time use and continuing therapy.
☐	**Humanitarian Use Device** (HUD) under a HDE	Non-research, on-label use of an HUD under a Humanitarian Device Exemption (HDE)
☐	Requesting Review by a **Non-UM IRB**	Use ONLY to request deferral of IRB oversight for UM activities to a non-UM IRB or when UM is a performance site in a multisite research project where UM is the lead site.
☐	**Multi-site Research** where U-M is a Coordinating Center and/or IRB of Record	Do not use Multi-site Research application type when U-M is **only** a performance site - select Standard application type. Select when U-M is any of the following: • Data Coordinating Center; • Clinical Coordinating Center; or • IRB of Record for non-U-M sites (for U-M to be IRB of Record you must contact your IRB for prior acknowledgement). When U-M is **also** a performance site, a separate application is required for local site considerations. Refer to special requirements at the IRB website.

View: 01-2. Standard Study Information
Section: 01. General Study Information

01-2. Standard Study Information

1-2.1* Who initiated this study?

Investigator

1-2.2* Are you or any students working on this project being paid from a federally funded training grant?

○ Yes ● **No**

1-2.3 This study is currently associated with the following department. To associate this research with a different department, click Select. If the department has defaulted to "student", click select to specify the department through which this application is being submitted.

Hlth Behavior & Hlth Ed Dept

1-2.5* Is the study related to cancer, cancer risk, or cancer care delivery?

○ Yes ● **No**

1-2.7* Has the scientific merit of this study already been peer reviewed (i.e., reviewed by one or more recognized authorities on the subject)?

● **Yes** ○ No

1-2.7.1* List the peer-review organization(s).

Peer Review Organization
External sponsor review process (e.g. study section)

1-2.8* Is this a clinical trial?

● **Yes** ○ No

1-2.8.1* Please select the trial phase

	Trial Phase	Description
○	Early Phase 1	Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). Exploratory study to determine if agent behaves in humans as pre-clinical testing indicated.
○	Phase I	Initial studies to determine the metabolism and pharmacologic actions of drugs/agents in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.
○	Phase I/II	Trials that are a combination of phases I and II.
○	Phase II	Controlled clinical studies conducted to evaluate the effectiveness of the drug/agents for a particular indication or indications in participants with the disease or condition under study and to determine the common short-term side effects and risks.
○	Phase II/III	Trials that are a combination of phases II and III.
○	Phase III	Includes trials conducted after preliminary evidence suggesting effectiveness of the drug (or other agent) has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug (or other agent).
○	Phase IV	Phase IV: Studies of FDA-approved drugs (or other agents) to delineate additional information including the drug's (or other agents) risks, benefits, and optimal use.
●	**Other/NA**	**Trials without phases (for example, studies of devices or behavioral interventions).**

If other, please specify:
This is a behavioral intervention study expanding on existing evidence-based program.

View: 02. Sponsor/Support Information
Section: 02. Sponsor/Support Information

02. Sponsor/Support Information

The following sections request details about the current or pending sponsorship/support of this study. Consider all of the choices below and complete the appropriate sections.
*** Note: At least one of the following sections must be answered. Multiple forms of funding or support must be added one at a time.**

2.1 Please select all Proposal Approval Forms (PAFs), Awards (AWDs), and/or Unfunded Agreements (UFAs) associated with this study.

☐ **Click here to indicate that a PAF(s) has not been initiated.**

Related PAFs:

ID	Title	PI	Direct Sponsor	Prime Sponsor	State	Has SUBKs?	Related Awards
19-PAF07406	Youth Empowerment Solutions: Engaging Youth for Anti-Racism And Cultural Equity (YES-ERACE)	Marc Zimmerman	Health and Human Services, Department of-National Institutes of Health		Awarded	no	AWD016412 (9/24/2020 - 3/31/2025)

Related AWDs:

Award ID	Title	PI	Direct Sponsor	Prime Sponsor	State	Has SUBKs?	Project Period	Awarded PAFs
There are no items to display								

Related UFAs:

UFA ID	Title	PI	State	Category	Start Date	End Date
There are no items to display						

2.2 Internal UM Sponsor(s)/Support: [Including department or PI discretionary funding]

Type	Department Sponsor	Support Type
There are no items to display		

2.3 Check here if the proposed study does not require external or internal sponsorship or support:

☐

2.4* Is there any other financial or non-financial sponsorship or support not covered in the sections above?

○ Yes ● **No**

View: 03. UM Study Functions
Section: 03. Performance Sites

03. UM Study Functions

3.1* Indicate all functions that will be performed at University of Michigan locations.

Select all that apply:
Recruitment (including screening)
Interaction (e.g., information gathering, survey, interview, focus groups, etc.)
Qualitative research (e.g., 'member checking', open-ended questions, etc.)
Secondary data collection (e.g., medical chart review, data abstraction from existing records, etc.)
Primary or secondary analysis (data/specimen)
Storage (data and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify.

View: 03-1. Performance Sites
Section: 03. Performance Sites

03-1. Performance Sites

3-1.1* Performance Sites:

Location	Country	"Engaged" in the research?	Performance Site Type	Site Function
Genesee Intermediate School District	USA	yes		Intervention,Interaction,Recruitment
University of Michigan	USA	yes		Qualitative research,Storage,Interaction,Analysis,Secondary data collection,Recruitment

View: Performance Site Detail
Section: 03. Performance Sites

Performance Site Detail

3-1.2* Location or Institution:

Genesee Intermediate School District

3-1.3 Address:

City
State
Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:

Recruitment (including screening)

Interaction (e.g., information gathering, survey, interview, focus groups, etc.)

Intervention (e.g., use of drug or device, medical procedures, educational intervention, group intervention, social/psychological intervention etc.)

If other, please specify:

3-1.5* Will this site be "engaged" in the conduct of the research?

● **Yes** ○ No

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version
AME00117777 GISD letter of support.pdf(0.02)	0.02

View: Performance Site Detail
Section: 03. Performance Sites

Performance Site Detail

3-1.2* Location or Institution:

University of Michigan

3-1.3 Address:

City
State
Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:

Recruitment (including screening)

Interaction (e.g., information gathering, survey, interview, focus groups, etc.)

Qualitative research (e.g., 'member checking', open-ended questions, etc.)

Secondary data collection (e.g., medical chart review, data abstraction from existing records, etc.)

Primary or secondary analysis (data/specimen)

Storage (data and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify:

3-1.5* Will this site be "engaged" in the conduct of the research?

● **Yes** ○ No

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

FWA00004969

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version
There are no items to display	

View: 05. Research Design
Section: 05. Research Design

05. Research Design

5.1* Is there a stand-alone scientific protocol document and/or research plan associated with this application?

● Yes ○ No

5.1.1* Click ADD to attach the document(s) electronically.

Name	Version
Ame00114207 PROTOCOL YES ERACE_ Program Development and Process Evaluation 7.8.21 Clean Copy.docx(0.03)	0.03
AME00117777 YES-IDEAS Protocol for IRB_12.3.21 Clean Copy.docx(0.02)	0.02
YES-ERACE Protocol for IRB 4.26.21.docx(0.01)	0.01

5.1.2* Indicate the section where each of the following are covered in the attached protocol:

Objective

The purpose of this study is to evaluate the efficacy of YES-ERACE (Youth Empowerment Solutions for Engaging Youth for Anti-Racism and Cultural Equity) compared to regular summer programming in increasing youth empowerment, promoting anti-racist behaviors, and decreasing youth violence.

Through the YES (Youth Empowerment Solutions) program, youth design and implement their own projects to help improve their own communities. We will adapt our existing YES curriculum to empower youth from diverse backgrounds to address racism and racial discrimination as a way to reduce violent behavior, including race-based victimization. YES-ERACE will focus on middle school students.

Our study will include two phases: 1) adapting YES and 2) testing YES-ERACE effects. Phase 1 will include evaluating curriculum revisions through testing new modules and obtaining feedback from youth and teachers. Phase 2 will test the effects of YES-ERACE using a group-randomized trial in non-academic summer programs across 6 middle schools. YES-ERACE projects will be youth-driven. We will examine the effects of the curriculum on individual youths' sense of empowerment, racism attitudes, and violent behavior. Finally, we will examine dose-response and sustainability of YES-ERACE effects.

AME00117777- We now refer to the program as YES-IDEAS (Youth Empowerment Solutions for Inclusion, Diversity, Equity, Appreciation, and Solidarity) instead of YES ERACE.

Specific Aim/Hypothesis

The study aims are to (1) adapt the YES curriculum to integrate several modules from the Learning for Justice curriculum (formerly Teaching Tolerance); (2) test the efficacy of the YES-ERACE curriculum in a randomized design on empowered outcomes which will mediate the effects of YES-ERACE on perpetration of racist attitudes and behavior; (3) investigate if empowered outcomes are the mechanism by which the YES-ERACE curriculum reduces racist behavior and aggressive and violent behavior (especially those motivated by racism) over time; and (4) study the effects of dose-response over time on the outcomes from AIMS 2 and 3. We expect findings from this study will provide evidence for a program to celebrate racial diversity based on empowerment that will reduce discrimination and racially motivated aggression in racially diverse middle school youth.

Empowerment theory includes processes that enable effective participation in community change efforts.23 Empowering processes engage individuals in activities that help them develop confidence, skills, and behavioral strategies to achieve goals.23 Empowering processes for adolescents include organizational and community involvement which provide safe and supportive contexts for interactions with positive adult role models.20,22,23 A process is empowering if it helps youth develop the cognitive skills necessary to critically understand their environments and become independent problem solvers and decision makers.23 It also provides a model for identifying and measuring outcomes relevant for specific populations and settings.22 Empowerment theory has been applied effectively in programs to prevent HIV/AIDS among Mexican men,80 youth alcohol and substance use,81 and youth violence.24,82

PI Zimmerman (1995) proposed a measurement model of psychological empowerment (PE) that includes 3 components--intrapersonal, interactional, and behavioral--expected to result from the empowering processes. The specific operationalization for each of these components differ depending on the context, population, and focus of interest.22,83 Generally, empowered outcomes include one's beliefs about themselves in relation to their social contexts (intrapersonal component), awareness about social relationships and the role they play to enhance (or limit) one's efforts to achieve one's goals (interactional component), and action to fulfill one's goals (behavioral component). In an RD context, the intrapersonal component includes beliefs about multiculturalism, stereotyping, and prejudice, the interactional component focuses on confidence in cross-cultural relationships and awareness of privilege, and the behavioral component focuses on inclusive behavior and bystander intervention when racism is observed. The adapted YES curriculum will incorporate modules designed to enhance attitudes of diversity, equity, and inclusivity, help youth think critically about their actions,

school, and community, and work with adults to implement projects they design to undo racism.

Our study is guided by the conceptual model in Figure 1. We hypothesize that YES-ERACE will increase psychological empowerment (PE) and that these empowered outcomes will reduce racist perpetration which will be associated with less violent behavior (especially race-related violence). We will also test the direct effects of the YES-ERACE program on racism and violent behavior. This progression is expected because YES is organized in a linear fashion beginning with helping youth develop confidence and skills, and culminating with project implementation focused on improving race relations and reducing racism. Our project will have two phases. Phase 1: Adapting YES-ERACE, which will not include any participant data, and Phase 2: Documenting implementation and testing the model in Figure 1.

AME00117777-We now refer to the program as YES-IDEAS (Youth Empowerment Solutions for Inclusion, Diversity, Equity, Appreciation, and Solidarity) instead of YES ERACE.

Background Information

Youth violence as a public health concern in the U.S is widely supported by epidemiological data.1 In 2015, nearly 23% of youths reported being in a physical fight, 16.2% reported weapon carriage, and 5.3% reported carrying a firearm on one or more days a month.2 Rates of bullying on school property (19%) and social media (16%) are also prevalent among youth.2 Short and long-term psychological (depressive symptoms),3 social (socioemotional adjustment),4 and developmental (impulse control)5 consequences of violence have been consistently documented. Racial minority youth are disproportionately more likely to be exposed to violence than non-Hispanic White youth.2 Homicide, for instance, is the leading cause of death for African Americans (AAs) from ages 10 to 24 and is a top three cause of death for Hispanic and American Indian/Alaska Native youth.2 AA, Hispanic, and American Indians/Alaska Native youth are also more likely to report physical assaults, school fights, and weapon carriage than non-Hispanic White youth.2

Racism and Violence. Experiencing racism, defined as “the exercise of power against a racial group defined as inferior”34, is associated with aggression and violence among racial minority youth.6–12 Racism, which can entail racial prejudice and discriminatory encounters, is a common experience for racial minority youth.35–37 Racism may lead to youth violence in 3 ways. First, interpersonal racism is a significant source of psychological stress38 which can increase the risk for violent behaviors.7,8 Second, the legacy of institutional racism (e.g., segregation) results in racial minority youth to be more likely than majority youth to encounter community-level risk factors associated with violence exposure and perpetration.13,39 Third, racism can cultivate interracial mistrust, fear, and hostility, resulting in violent behavior.14,15
Racial Prejudice: Racial prejudice refers to conscious and unconscious negative attitudes and biases ascribed to members of racial groups. Researchers have documented the adverse effects of racial prejudice on interracial mistrust and disrespect,40–42 fear,43,44 and violence.45 Raabe & Beelmann (2011) noted that racial prejudice can develop in children as young as 3- and 4-years of age.46 To understand the formation of racial prejudice, Tajfel’s (1979) seminal theory on social identity posits that the construction of in and out groups (i.e., us & them) during early developmental periods play an important role in developing a social identity.47 Race and class are often the basis of group identity formation. It has been argued that the development of in- and out-groups can also shape prejudicial attitudes, especially towards members of outgroups. Consistent with this line of thinking, embracing exclusionary norms (e.g., race) has been associated with increased dislike48, bullying,49 and aggression50 towards outgroup members. It is, thus, plausible that racial prejudice may exacerbate youth violence by cultivating interracial distrust, tension, and conflict among racially diverse youth.

Early adolescence (10-13 yrs) is a critical life stage to examine racial prejudice and youth violence. Identity development with respect to race primarily involves discovering and understanding the significance and meaning of race within a racialized society.51 Racial identity development is a multidimensional process51 that may offer psychological and physiological protection within the context of racism-related stress.53,54 AAs strong sense of collective group identity, for example, moderated the influence of RD on violent behaviors.7 This suggests that enhancing racial identity development may help reduce the negative effects of RD and, concomitantly, youth violence. Researchers have noted that racial identity development can also consolidate negative racial norms that can contribute to the development of racial prejudice.52 Youth Empowerment Solutions (YES) is one program that integrates exercises for positive racial identity development throughout the curriculum in a way that attends to tolerance and pride as a way to mitigate these negative effects.25,26

Racial prejudice can also be partly explained by institutional policies that promote neighborhood and school segregation55 which can result in limited interracial interactions between youth. Researchers have reported that less interracial contact induces more racial prejudice in youth.56 Severing the development of racial prejudice from the racial identity process, and developing interracial contacts through collaborative projects may reinforce interracial understanding and advance the prevention of youth violence.

Stress (Interpersonal Racism): Researchers have documented the emotional and mental health consequences of experiencing racial discrimination (RD) among minority youth.57 Racial discrimination, for instance, has been associated with higher levels of negative affect53 internalizing problems58,59, and externalizing problems60,61 in racial minority youth. In a separate line of studies, negative affect and internalizing and externalizing problems have been associated with aggression and violent behavior among youth.62 Unaddressed and prolonged emotional injury invoked by RD may elevate anger, hostility, and violent behaviors in racial minority youth.62 This is consistent with Harrell’s (2000)38 conception of race-related stress which posits that routinely encountering RD may tax or exceed the youth’s coping resources, which worsens psychological well-being and heightens vulnerability for engaging in violent behaviors. Efforts to address the psychological consequences of RD are necessary to disrupt the link between RD

and youth violence.

Contextual Risk Factors (Institutional Racism): Researchers have also increasingly recognized the influence of structural racism on youth violence.8 AA and Hispanic youth are more likely than White youth to reside in racially isolated and socioeconomically disadvantaged neighborhoods marked by a higher concentration of poverty, violence, crime, inferior municipal services, and limited access to quality educational, health care, and recreational resources.63 These neighborhood characteristics are risk factors for youth violence.45,64–66 Many theories explain the association between neighborhood disadvantage and youth violence, however, Andersons' (1999) Code of the Street details features of neighborhood disadvantage that can facilitate a subculture of violence.67 Specifically, when concerns of safety, belonging, and deprivation are pervasive, the code of the street conceives of violence as a method to self-protect, obtain desirable possessions (money), and gain status (respect). A large proportion of youth residing in impoverished neighborhoods also report distrusting the police and legal system and, as a result, use violence to resolve disputes.68 Thus, as many racial minority youth reside in disadvantaged neighborhoods due to ongoing institutional racism they are also more likely to contend with the contextual risks associated with violence than majority youth. Researchers have found that community engagement, however, may help moderate negative neighborhood influences.69 Our project is designed to enhance youth involvement in community improvement.

Youth Empowerment and Violence. Empowerment theory applied to youth development suggests that planning and implementing community development projects will help youth gain vital skills, responsibilities, and confidence necessary for positive youth development. Our proposed intervention is intended to empower youth by helping them gain skills in developing community change plans, identifying resources, and working with adults to implement projects designed to reduce racism and gain a greater understanding of and appreciation of racial diversity. Empowering processes are consistent with the NRC/IOM70 characterization of successful positive youth development. Evaluations of empowerment-based interventions indicate that engaging youth in community service activities can reduce violent behaviors and other violence-related psychosocial outcomes.71–75 Researchers suggest that middle school aged youth can be engaged in a range of community improvement activities with positive outcomes including needs assessment, strategic planning, program development16–18 and are capable to engage in youth-driven projects.27,28 Our initial studies of YES described how the curriculum engages middle school aged youth in developing a critical understanding of neighborhood violence and designing and implementing neighborhood and school improvement projects to reduce violence19-25. Our research also demonstrated that YES had positive effects on youth (less violent behavior, more positive behaviors) and neighborhoods (reduced violent crime incidents, improved property maintenance)26. Preventing problem behaviors early is vital to promote mental health and prevent psychological distress76. Empowering youth to address violence at this critical developmental period may enable them to resist negative behaviors in their school and community. We will adapt our empirically tested YES curriculum to address racism and racial discrimination for racially diverse middle school youth.

Youth Empowerment and Racial Discrimination (RD) Interventions. Few, if any, researchers have applied a theory driven empowerment program to the topic of racism.25 Our YES curriculum is well positioned for this adaptation because: 1) it includes ethnic identity and multiculturalism; 2) we have adapted it for several outcomes; and 3) we developed an adaptation guide to support systematic adaptation while maintaining fidelity to the curriculum's core components. School-based interventions offer tremendous opportunity to reduce risk of multiple forms of violence among youth, including violence as a result of racial/ethnic prejudice, as they reach large populations of adolescents, including those underserved by other settings.77 Although interventions to support diversity, equity and inclusion exist, few are designed for youth and even fewer have been evaluated with strong designs.78 Understanding connections across forms of violence (e.g., racially motivated aggression) is a central tenet of recent initiatives to identify cross-cutting approaches for prevention.79 Thus, efforts to integrate prevention approaches across forms of violence is emerging. Our objective is to adapt systematically the YES violence-prevention EBI using key adaptation steps described in implementation science frameworks to integrate the Learning for Justice curriculum33 and test if the adapted YES curriculum (YES-ERACE) reduces racial discrimination and racially motivated aggression.

The rigor of this prior research on racism, violence, and health and mental health outcomes is high because it included various samples, slightly different measures and approaches, and resulted in similar findings. Thus, research on the health risks and consequences associated with racism are robust. The research on empowerment and YES in particular, is also robust because results have been consistent across different implementations of the curriculum. Consequently, the scientific premise for our study is founded on a solid conceptual and empirical foundation, and builds on that work in significant and unique ways.

The proposed project is innovative in several ways: 1) we integrate Learning for Justice modules with our evidenced-based YES curriculum guided by empowerment theory which is a natural advancement for the curriculum because it already involves modules on racial identity development; 2) we adapt YES, originally designed to focus on violence prevention, to focus on RD and race-related violence and appreciation of diversity; 3) we apply implementation science frameworks for adapting YES which is unique because most adaptation research has focused on using frameworks to make cultural adaptations, but not necessarily addressing a new issue being added to a program; 4) we test the adapted curriculum during non-remedial summer school sessions so the program can be feasible to deliver and sustainable overtime with minimal resources and without the many issues of implementation during the school day; 5) we test a theoretical model that suggests a mechanism for reducing violence through the process of empowering youth to make community changes focused on undoing racism that they develop and implement; and 6) we involve an Advisory Board (described below) of undoing racism practitioners and youth to guide our work and

who can provide a model for other groups interested in incorporating similar modules in their programming. Another innovation is our interdisciplinary research team also brings together expertise in racial discrimination, intervention, and positive youth development. The research team includes the founders of the YES program (Zimmerman, Reischl). Co-Is Caldwell, and Anderson bring expertise in racial discrimination and racial identity. Co-I Eisman brings expertise in implementation science. Our team also has a longstanding collaboration with our school district partners. Our advisory board will further help guide the project.

AME00117777-We now refer to the program as YES-IDEAS (Youth Empowerment Solutions for Inclusion, Diversity, Equity, Appreciation, and Solidarity) instead of YES ERACE.

Methodology

Phase 1: Adapting the YES Curriculum (Aim 1). We will revise the existing YES curriculum to include lessons on racism perpetration, and appreciating and celebrating differences. We will use the ADAPT-ITT (Assessment, Decision, Adaptation, Production, Topical experts, Integration, Training, and Testing) framework to guide adaptation of YES, expanding the scope of the intervention to address racial/ethnic discrimination.86 This framework is useful in guiding the process of tailoring an intervention while keeping intact its core effective elements.87 We have assembled an Advisory Board of local leaders involved in undoing racism work and Learning for Justice (see letters of support). Our Advisory Board includes: James Yake, GISD Superintendent; Sue Peters, Vice President of Community Impact, Community Foundation of Greater Flint and Jessyca Matthews, English teacher at Carman Ainsworth High School in GISD with expertise in Learning for Justice. Ms. Matthews will train our team on Learning for Justice modules that we will incorporate into YES. Ms. Matthews was named the Teacher of the Year for 2018 by the MI Council of Teachers of English (MCTE), and a 2017 Social Justice Activist of the Year Nominee. In 2017, her students collaborated with students in Lansing, MI, to advocate for clean water during the Flint water crisis. She has written two books and co-wrote the play Appointments: An Accountant of the Flint Water Crisis to raise awareness of the crisis. We will also consult with Dr. Enrique Neblett, Associate Professor of Psychology and Neuroscience and Lab Director of the African American Youth Wellness Laboratory at the University of North Carolina at Chapel Hill. His research examines the link between racism and health in African American youth. He also teaches courses on racism and racial identity. Dr. Neblett is an Associate Editor for Cultural Diversity & Ethnic Minority Psychology CDEMP and on the Editorial Board for the Journal of Black Psychology. Dr. Neblett provides our team with additional expertise in racism, racial identity and adolescence, and will help guide the development and adaptation of the curriculum. We will also work with our school partners to identify local youth to advise us on the adaptation of the curriculum.

Adaptation of the intervention will follow the ADAPT-ITT process which includes 6 steps: 1) We will assess potential barriers to implementation through interviews with school personnel to develop a comprehensive understanding of resources and issues regarding promoting diversity, equity and inclusion (DE&I) among middle school students. We will work with our Advisory Board to apply this information for informing decisions about YES-ERACE adaptations. 2) We will conduct initial administration of key novel intervention components with middle school youth who will not be in the study and obtain feedback from youth regarding acceptability, satisfaction, relevance, and appropriateness of new integrated content. This information will guide further adaptations of YES. 3) We produce a detailed manual and all related instructional materials (student handouts, supplies lists) for the new YES-ERACE curriculum. We will also develop our evaluation materials (e.g., measures, fidelity) and training protocol during this stage of adaptation. 4) We will ask our topical experts (i.e., Advisory Board) to provide context in interpreting the development data and feedback regarding the new YES-ERACE modules. 5) We will take all this information and integrate the feedback to develop an updated curriculum. 6) We will conduct trainings and feedback sessions for the new modules program with middle school students and teachers in Genesee County. We will ask youth to provide feedback about what they liked and did not like about the new modules, as well as give feedback regarding their comprehension of the questionnaire. This information will be used to guide additional revisions to the curriculum and questionnaire for Phase 2. We have used a similar approach in developing the original YES curriculum.

Phase 2: Testing YES-ERACE Efficacy (Aims 2 & 3). We will randomly assign schools to YES-ERACE or the standard summer enrichment program (i.e., attention control). Parents will be consented when they sign-up their child for their school summer program. Youth will be assented on the 1st day their summer program. Each school assigned to YES-ERACE will have a dedicated YES-ERACE program teacher and will not teach any other summer program at the school. All 6-8th grade students attending the summer program will be eligible for the study. If parents or students opt out of the study, they will still be allowed to enroll in and attend their school's summer program; however, they will not complete any questionnaires, and they will not be included as part of the study's participants.

Schools will remain in their assigned condition for all 4 years of study implementation. In year 5 all schools will receive the YES-ERACE intervention. Youth who attend YES-ERACE in multiple years and participate in the study will receive the program more than once (and up to 3 times). We will analyze the data to test dose effects as an independent variable to take the repeat exposure into account. Scientific Rigor: Data analyses examining treatment effects in this study must also take into account potential clustering, or correlations among observations within a given group (i.e., intraclass correlations or ICC's) due to factors common to a program context (e.g., school culture, teacher effects). Our previous work with GISD schools testing YES indicated very small ICC's (.01) within the schools for our outcome variables of interest (except racist perpetration). Although these correlations are small, if an ICC greater than zero is ignored, the outcome variance due to between-group differences (which can be large) is mixed with outcome variance due to between-participants variability within the group (which can be small because of the correlation). This can lead to large standard deviations, larger p values, and false-negative results.89. Thus, our analytic strategy described below considers the ICC to account for the effects

of clustering on individual intervention outcomes. Effectiveness studies of group-based interventions have often employed group-randomized trial (GRT) research designs which randomly assign groups (schools) to different treatment conditions. GRT designs, however, often require a large number of groups to achieve adequate statistical power90,91 and can be cost prohibitive. The design we propose is a more cost-effective and viable design, as long as the ICC is accounted for, as we intend to do.92

Study Context: Genesee County Intermediate School District (GISD). GISD administers and summer programming in Flint and Genesee County. The study will take place during the non-academic summer program (NASP) in 6 middle schools in Genesee County, MI. Genesee County's population of 429,000 has remained flat since 1990.93 Flint is the county seat. We selected schools with non-academic summer programs with some racial diversity to increase interracial collaboration. Table 1 includes demographic characteristics of the 2017 non-academic summer programs at our proposed 6 study schools. The GSID has indicated that the size and
Table 1. Demographic data for all study schools (*6th grade only).

School Students per Summer Demographics
YES-ERACE
Carman/Ainsworth 75 53% AA, 30% White, 10% Multi-Racial, 7% Other
Genesee 12* 2% AA, 89% White, 9% Other
Atherton 61 21% AA, 46% White, 28% Multi-Racial, 3% Other
Westwood Heights 54 96% AA, 4% Unknown
Bendle 25 20% AA, 80% White
Kearsley 30 80% White, 20% Other
Total = 257/year
composition of the summer program going forward will be roughly the same as these are representative of historical statistics. We have worked with GISD staff implementing the original YES program over the last 7 years. GISD and staff from the individual schools participating in this study will be active partners in all phases of the research study. Districts will help enroll students into the study and specially trained GISD staff will deliver the YES-ERACE curriculum as a part of their summer program. The same individuals will NOT provide both YES-ERACE and the usual summer program. Youth in the control arm of the study will participate in the usual non-academic summer programming offered by the schools.

Summer Program. We chose to work in the summer program for several practical and methodological reasons even though we do understand that the students in such program may not generalize to all students. Yet, they may be youth who have the highest need due to both parents/guardians working or a single parent/guardian working and they cannot afford a more expensive option such as summer camp. First, summer programs provide an opportunity to have a captured audience of youth in a structured program. This allows us to create an intensive experience for youth without interfering with the demands of the many school requirements during the year. It also does not require an after-school setting that may interfere with extracurricular activities as we have experienced in the past. Second, the summer school setting provides a controlled setting with a dedicated teacher. It also allows us to hire graduate students to assist the teachers without interfering with their coursework. Although graduate students may not be a sustainable approach once the study ends, it is realistic for larger summer programs to hire support for the main teachers. Graduate students provide us with more control of implementation which is important for the research fidelity in a real world context. Third, the program is self-contained with the summer period which allows for youth project development and implementation to occur during a shortened period of time with fewer demands and good weather. When YES is implemented during the school year we may have to wait for the weather to improve if it is an outdoor project which pushes the activity to the end of the school year.

Co-I Stoddard has experience implementing YES adapted for a focus on future orientation (YES- Possible Futures; YES-PF) in a summer program that was 4 hours/day, 4 days/week over 5 weeks. She found it is feasible and acceptable to both students and school personnel.94 She also found that student attendance was very good (50% of students attended every day of the program & 36% of students missed only 1-2 days). Most students liked learning about multiculturalism (84%), leadership (84%), school assessment activities (89%), and planning and completing the school change project (90%). These are all core components of YES. Almost 80% of students found the program to be very or extremely helpful for building social skills. The majority of the students reported they would recommend the program to a friend. Summer program teachers reported high student enthusiasm and engagement in program. They also reported liking the program and said it was fun to teach because it was different from some of the typical academic-focused summer school programs.

Sample. We will involve all 6th-8th grade students attending non-academic summer programming (NASP) in the study. The YES-ERACE schools will remain in their condition for 5 years and the control schools will remain controls for 4 years then in year 5 they will receive the YES-ERACE program to be sensitive to practical considerations for the schools waiting to get the program. Our Genesee Intermediate School District (GISD) partners have indicated that most summer school participants are 6th graders and that few 8th graders attend so that each year new students are replenishing the summer program cohorts. Thus, we will have youth who repeat if they attend summer program after their 6th grade year. This means some youth will receive more YES-ERACE dose that others, and that control youth will be control youth from one year to the next. This design allows analysis of dose-response effects for the YES-ERACE intervention (AIM 4).

Student Recruitment. Students will be recruited to participate in the study after they have signed up for their summer program, but before it begins. Parent/guardian consent for student participation in all assessments will be obtained at the time of recruitment by sending letters home in the summer programming announcement packet sent out by schools. The letters will include information about the study and procedures for returning signed consent. We will follow up this mailing by calling parents who have signed their child up for the

summer. We will also hold study orientation meetings for parents at the six schools (to coincide with other parent-school activities), attend spring events at schools, and advertise the study in school mailings so we have multiple methods of informing students and their families about the study. Only students whose parents have consented will be recruited to assent to participating in the study by completing the questionnaires. Based on guidelines from the CONSORT Group,95 sample information to be assessed at the end of the study will include 1) number of youth in the summer program (i.e., eligible), 2) number of families completing consents, assents, and baseline assessments, 4) number of youth receiving the YES-ERACE or usual summer program, and 5), number of youth lost to follow-up. We will conduct attrition analyses to assess group differences (see Data Analysis section).

Strategies for Longitudinal Tracking and Retention. Based on GISD's long history with summer programs, PI Zimmerman's extensive experience running longitudinal studies in Flint over several years, and our team's past experience implementing the YES program in this setting, we anticipate an attrition rate below 15%. Yet, we expect much lower attrition because we will be following youth for less than 1 year with only two post-tests during the school year after the immediate posttest in the summer. We have found the curriculum process enhances motivation and maintains youth involvement because we: 1) provide snacks; 2) include time for youth sharing; 3) include art projects and other creative activities as part of the lessons; 4) incorporate small celebrations throughout the program; and 5) have a large community celebration at the end of the program. Process evaluations of previous YES implementations indicated that students typically enjoyed and were engaged in the program.24 In addition, we work closely with the GISD so we will know what schools the student may have moved to while they are still in middle school and what school they are attending once they enter high school (for the 8th graders in the study). We will also use a graduated incentive structure to enhance youth participation. All participants will be given financial incentives to complete questionnaires, with incentives increasing for each additional assessment ($5 for Pretest, $10 for immediate post-test, $15 for completing Fall post-test, and $20 for completing Spring post-test). Participants who complete all study waves will also be entered in a drawing for a $50-$100 gift certificate at a local mall (multiple prizes will be available). Participants who fail to complete consecutive assessments will still receive the larger incentives to complete later assessments given the value of these data points to test longitudinal hypotheses, but they would not be eligible for the bonus prizes. Finally, we will obtain address, phone, and email information for three people who could reach participants if they move. We will also employ multiple contact strategies during the school year, including phone calls, text messages, emails, and personal contact at schools. School year post-tests will be collected via the web so that data collection does not interfere with school and students can complete the questionnaire at a time convenient for them.

If we have a conservative estimate of 1/3 renewal from 6th grades and 1/3 leaving from 8th grade in each cohort, our sample size of unique individuals with at least 4 data points would be 295 for the YES-ERACE
Table 2. Sample size projections over 5 years.

YEAR YES PROGRAM CONTROL
1 148 109
2 49 36
3 49 36
4 49 36
TOTAL 295 217
condition and 217 (109 in year 1 + 36 new youth for 3 more years) for the control condition (Table 2). If we estimate a conservative 20% attrition rate due to all causes we will have 236 youth receiving YES-ERACE and 174 in the control condition who will have pretest data and 3 post test data points (total N = 410). A 20% attrition rate, however, is quite conservative because: 1) our past attrition rates for all causes has been about 10%; 2) we estimated only 1/3 renewal rate per year which assumes equal numbers of youth attending by grade, but GSID has told us that far fewer 8th graders are in the summer program and almost half of the summer program in any one year are 6th graders (and one school only has 6th graders so they will have 100% renewal annually); and 3) we expect high retention rate for data collection because we are only following youth for 1 school year (most of whom will be in the same school as the summer program), the first 2 data points are close together, and we have excellent success with these strategies working with the GSID. Our past work with GISD resulted in over 90% response rates over 4 years using similar strategies.96 The GISD will help locate youth after the first posttest data collection if youth move schools. Thus, we expect similar or better retention rates in this study.

YES-ERACE Intervention Staff Training. We will train 3 facilitators hired by the schools and 8-10 graduate students to assist them in delivering the YES curriculum. We will expand our existing YES training materials for implementing YES-ERACE. The training will include 3 half-days with workshops that focus on curriculum philosophy, theory and goals, flow and content, and practice implementing modules including activities specific to Learning for Justice. The training includes doing some of the activities and role playing to demonstrate how to allow youth voice and governance while also maintaining discipline. The first workshop will focus on empowerment theory and its application for youth, a read through of the curriculum, and discussion of our experience implementing YES. The second workshop focuses on the first 3 modules and the program planning modules. The third workshop will introduce the goals of undoing racism and the Learning for Justice modules, and include practice implementing these sessions. Staff will be hired and trained before the summer programs begin each year. All workshops include discussion and debriefing. We will also provide technical assistance to facilitators on an ongoing basis. The graduate students' will provide support to the teachers for implementation of the curriculum including assistance with fulfilling project activities.

Intervention Implementation. The YES-ERACE intervention will be delivered over the course of the summer program. This will also include implementation of the student projects. Students assigned to YES-ERACE will be assigned to groups of 10-12 students. In cases where a teacher may have more than 2 groups, we will

provide graduate student assistants (GSA) to help guide the groups through the program activities.24 Students in the control condition will receive the usual summer program at their school. We will evaluate YES-ERACE implementation by examining multiple dimensions of fidelity guided by the Implementation Outcomes Framework, including adherence, quality delivery and dose delivered.97 We will also assess adherence to YES-ERACE protocol, quality of delivery, and dosage.97 We will measure adherence, the extent to which the intervention was delivered as intended97 using implementation logs completed by GSAs to assess the number of modules and core components implemented. We will assess quality of delivery by having trained GSAs use a coding system to assess student-teacher interactions. We will also assess dose delivered per individual.98 Dose delivered will be the attendance reported by facilitators. We will also assess dose received to provide information about individual participant exposure to the program content and give an indication if participants were sufficiently exposed to the intervention.99 We will measure dose received at the first posttest by asking youth to indicate if they participated (yes/no) in YES-ERACE activities and a rating (5-point Likert scale) of how much they liked each key activity of the curriculum: 1) identifying community assets; 2) Photovoice; 3) multiculturalism and Learning for Justice modules; and 4) planning and completing the project. Youth will be given a dosage score, which reflects their cumulative exposure to the YES-ERACE curriculum. For instance, youth who complete all 6 YES-ERACE units in year 1, but only 3 units in year 2, would have a dose score of 6 in year 1 and 9 in year 2. Participants in the control condition will be given a dose score of 0. The dose score measures the intensity of exposure to YES-ERACE and allows us to approximate whether changes in outcomes are shaped by differing levels of exposure. We will analyze these dose measures separately and in various combinations to provide an in-depth analysis of dose response.

Data collection. We will collect data at 4 time points. The baseline pretest will be collected before students start the program. We will collect an immediate posttest 1-3 weeks after the youth complete the program. We will collect a second posttest 3-4 months after the immediate post-test, and a third posttest will be collected 8-9 months after the immediate posttest. The pre- and immediate posttest data will be collected with a paper and pencil questionnaire. The two other posttests will be collected using methods tailored to their preferred approach which will include: 1) Qualtrics and a link to the questionnaire to you in text messages and email (and possibly social media); 2) mailed questionnaire with return envelope; or 3) telephone on a secure line.

Measures. Measures of each component of psychological empowerment (PE), racism perpetration, and violent behavior (dependent variable) are described below and in the Appendix. We will also collect demographic data to use as covariates in analyses (i.e., sex, age, race/ethnicity, parent education). PE includes 3 components—intrapersonal, interactional, and behavioral—and that must be tailored to the specific context.20
The intrapersonal component includes empathy, cultural sensitivity, and prejudice. We will measure empathy using the Empathic Concern subscale, which assesses the emotional component of having sympathy for others (Davis, 1980). Cultural sensitivity will be operationalized with the interethnic ideology measure100 which assesses value for ethnic diversity, inclusion, and multiculturalism. We will measure lack of prejudice with the Other Group Orientation scale (Phinney, 1992), which assesses a person's attitudes about different ethnic-racial groups interacting with each other, and the Egalitarianism subscale of Critical Reflection (Diemer et al., 2017), which assesses attitudes toward equality.
The interactional component includes the ability to identify strengths in people, critical thinking about differences and privilege, and social connection across race/ethnicity. The ability to identify strengths in people will be measured with items we developed to assess youth's beliefs about appreciating other people, including other people's differences. To examine critical thinking about differences, we will use the Perceived Inequality subscale of Critical Reflection (Diemer et al., 2017), which measures participants' awareness of systemic inequality based on race/ethnicity, gender, and class. Social connection across race will be measured using the Cross-Ethnic Friendship Self-Efficacy Scale (Bagci et al., 2020), which assesses how well they relate to, communicate with, and befriend people from different cultures. We will also ask youth to report on the race/ethnicity of their five closest friends to assess if their friend groups become more or less segregated over time.
The behavioral component focuses on actions people may take that correspond to the attitudes and skills from the other two PE components and will be assessed with items that measure prosocial inclusive behaviors,105 social action for undoing racism and speaking up against injustice (Aldana et al., 2019), and bystander intervention behavior106.

Racism perpetration will be measured using short vignettes that allow participants to report on their attitudes toward various situations.

Violent Behavior. We will assess bullying with the scale used in Low and Espelage (2013) and violent behavior with Hurd et al. (2011). We will also adapt a scale of ethnic-racial teasing (English et al., 2020), which assesses individuals experiences of being teased because of their race or ethnicity. We will reword this scale to measure the participant as the perpetrator rather than the victim.

We also include a number of measures of positive behaviors and experiences, such as prosocial behavior (Taylor et al., 2018), Academic Engagement (Skinner et al., 2008), and Daily Positive Racial Experiences (English, 2017).

AME00117777- We are now conducting the study in the context of an after-school program at GISD, rather than a summer program.

AME00117777- We now refer to the program as YES-IDEAS (Youth Empowerment Solutions for Inclusion, Diversity, Equity, Appreciation, and Solidarity) instead of YES ERACE.

AME00117777- We removed the appendix from the protocol. The only measures that will be used are the ones currently in the approved questionnaire.

Statistical Design

Data Analysis Plan. Data analyses will be conducted using Mplus v8112. As a precursor to examining AIM 2, we will test our measurement model of

psychological empowerment (PE), racism perpetration, and violence using confirmatory factor analysis to develop measures used in testing specific hypotheses. We will also examine individual indicator variables to examine hypotheses for specific variables.

AIM 2: YES intervention effect on Empowerment. To examine the efficacy of the YES-ERACE intervention, we will estimate conditional latent growth models (LGMs) to assess whether receiving the YES-ERACE increased PE over time, while decreasing racism perpetration and violent behaviors. As a precursor to examining conditional LGMs, we will fit unconditional LGMs to determine optimally fitting trajectories for each outcome. We will evaluate model fit by examining the chi-square goodness of fit statistics (χ2)113 root mean square error of approximation (RMSEA)114, confirmatory factor index (CFI)115 and the Tucker Lewis Index (TLI).116 We will also conduct robust likelihood ratio tests (LRTs)117 to select parsimonious LGMs that fits the data well. Next, conditional LGMs will be estimated to investigate whether YES-ERACE, in relation to the control condition, influences the growth terms of PE, racism perpetration, and violent behaviors. Because participants will be recruited from six schools (i.e., 3 for YES-ERACE, 3 for control condition), we will address within-school correlations (ICC) by adjusting the chi-square statistics and standard error as recommended by Muthen and Satorra.118 The corresponding equation reflects the model that we will estimate:

Within-Subject Model: yti = η0i + η1iλt + εti
Between-Subject Model (Intercept): η0i = η0 + γ1(YES-ERACE)i + ς0i
Between Subject Model (Slope): η1i = η1 + γ2(YES-ERACE)i + ς1i

In the within-subject model, yti denotes the outcome for a participant (ith) at a particular time point (t), η0i and η1i are random coefficients that reflect the latent intercept and slope term, λt is a proxy for the variable of time, and εti denotes error in the within subject-model. In the between-subject models, the intercept and slope (η0i and η1i) serve as dependent variables, γ1 reflects the effect of YES-ERACE on the overall mean level of the initial outcome, γ2 reflects the effect of YES-ERACE on the average rate of outcome change over time, and ς0i and ς1i are error terms in the between-subject variations. If YES-ERACE has a significant effect on the slope of an outcome variable, we will test simple slopes between the control and YES-ERACE conditions by:

μyi|x = η0 + η1λt + γ1(YES-ERACE) + γ2λt(YES-ERACE)

We will probe the interaction between time (λt) and YES-ERACE by estimating simple intercepts and slopes for participants in the YES-ERACE and control conditions as shown in this reduced-form equation.119

AIM 3: YES-ERACE mediational model. To examine the mediational model from YES-ERACE to violent behaviors, we will first obtain growth factor estimates (e.g., model estimated intercepts, slopes) for each participant. We will then conduct a serial mediation analysis in which YES-ERACE reduces violent behaviors over time by increasing PE and reducing racism perpetration over time (see Figure 1). Specifically, we will test whether YES-ERACE accelerates improvements in PE, which diminishes racism perpetration over time. Additionally, we will examine whether accelerating decreases in racism perpetration accelerates decreases in violent behaviors as indicated in Figure 1. Like AIM 2, we will account for the non-independence in the individual-level data by controlling for within-school correlations. To evaluate the proposed longitudinal mediation from YES-ERACE to violent behaviors, we will conduct tests of joint significance (TJS).120 This test can determine whether the product of coefficients from individual paths (e.g., YES-ERACE slope of PE) within the indirect effect is statistically significant.121 The TJS method more power and yields lower Type 1 error rates than the bias-correct bootstrap method for estimating indirect effects.121 Chi-square goodness of fit statistics, RMSEA, CFI, and TLI will be examined to examine model fit.

AIM 4: YES-ERACE dose-response effects and sustainability over time. Conditional LGMs will be conducted to approximate the dose effect of YES-ERACE on PE, racism perpetration, and violent behaviors. We will also adjust the LGMs for time, demographic variables, and socioeconomic status. The participants' cumulative exposure to YES-ERACE units will range from 0 (i.e., control condition) to 24 (i.e., participant received all 6 YES-ERACE units in 6th, 7th, & 8th grades). We will build upon the unconditional LGMs from AIM 2 by including sociodemographic variables as time-invariant predictors and dosage as a time varying predictor:

yti = η0 + ∑γ0k(covariates)ki + η1λt + λt∑γ1k(covariates)ki + ∑βt(dosage)ti + (ς0i + λtς1i + εti)

The corresponding equation reflects the combined within and between subject models, in which yti is the observed outcome measured at time t for participant i; η0 and η1 two latent growth factors (intercept, slope); λt are time scores; γ denotes the effects of the covariates (e.g., sex) on the latent factors; βt denotes the effect of dosage on the corresponding yti; and (ς0i + λtς1i + εti) representing random components of the within- and between-subject growth trajectories. We will use the same model indices noted above to test hypotheses. Dosage will be analyzed using the individual dose measures noted and various combinations of them.

Attrition Analyses. Although LGMs can handle missing data using Full Information Maximum Likelihood (FIML), we will also examine attrition effects using t-tests and chi-square analysis to compare youth without Time 4 data with those who remained in the study. We will examine all study variables (including covariates) within the YES-ERACE and control groups, and between them to examine differential attrition across groups.

Power Analyses. AIM 2: We conducted a Monte Carlo (MC) simulation to evaluate the statistical power of a model in which YES-ERACE accelerates increases in PE, while decreasing racism perpetration and violent behaviors. For the outcome, we specified an intercept (baseline) and slope (rate of change) term for the LGM. We adjusted standard errors for non-independence and specified conservative effect sizes between YES-ERACE and controls for the intercept (.10) and slope

(.15) for each outcome. We also specified conservative mean intercept (.10) and slope (.05) estimates. The simulation with 10,000 replications and assuming only 80% of our projected sample of 512 (N = 410) produced ample statistical power (.95) for detecting a small effect of YES-ERACE on the rate of change for each outcome.

AIM 3: Our MC simulation to approximate the power of a serial mediational model in which YES-ERACE diminishes the slope (rate of change) of violent behavior by positively shaping the slope of PE and negatively shaping the slope of racism perpetration (see Figure 1). We specified conservative estimates for the slope (.03) and for associations between the slope factors (i.e., .15 to .20). After adjusting for the non-independence in the data, the simulation produced a power of .89 to detect an indirect effect from YES ERACE to the slope of violent behaviors (through PE and racism) with a sample size of 410 (80% of projected sample).

AIM 4: Our MC simulation to conduct power analysis for detecting dose effects indicated statistical power in the 83-.96 range for detecting dose effects on the outcomes at each time point. The LGM with time invariant (i.e., covariates) and varying (i.e., dose) predictors estimated the power for detecting a conservative slope term (i.e., -.05) with the 80% sample size (N=410). We also included conservative estimates for the time-varying effects of dose on the outcome variable at each measurement period (i.e., .05-.15). We specified 10,000 replications and adjusted for the non-independence in the data using a sandwich estimator.

Additional Study Considerations
Community implementation and budgetary limitations present several methodological challenges for ensuring confidence in the internal validity of our study. First, we do not have enough schools to be powered to test for school level effects, but this is not a significant issue because we are not studying school level outcomes and we will be testing our hypotheses with data weighted by the ICC within schools. Second, youth in YES-ERACE schools could receive the intervention more than once. This is handled in our data analysis as described for Aim 4 which provides an opportunity to study dose-response and sustainability of effects. Third, students may change schools that are in a different condition than where they started. This is an unavoidable problem which we expect to be limited as school stability is high in the districts where we are working. In addition, we will note such changes (school changed yes/no) and handle this in our dose-response analyses by examining if the results change when students who change schools are included or excluded from these analyses or will enter the change indication variable in the analysis as a covariate.

AME00117777- We now refer to the program as YES-IDEAS (Youth Empowerment Solutions for Inclusion, Diversity, Equity, Appreciation, and Solidarity) instead of YES ERACE.

5.1.3* Study team Experience: Briefly outline the experience and competence of the study team to pursue the proposed study.

Principal Investigator, Marc Zimmerman, Ph.D., serves as Principal Investigator for the YES-ERACE study. Dr. Zimmerman is former Chair and Marshall H. Becker Professor in the Department of Health Behavior and Health Education at the University of Michigan School of Public Health and Director of the CDC-funded Michigan Youth Violence Prevention Center and CDC funded Prevention Research Center. He is also PI of the BJA funded National Center for School Safety. He is the developer and PI of the Youth Empowerment Solutions (YES), an evidence based youth empowerment curriculum for middle school youth, which has been disseminated nationwide. Dr. Zimmerman will be responsible for the over-all direction of the research, adaptation and implementation and evaluation of the curriculum. He will assure the effective coordination of all operations and the integration of all partners in the work and provide leadership on the evaluation and analyses of the data.

Co-Investigator, Abunya Agi, PhD., is a postdoctoral fellow in the Department of Health Behavior and Health Education at the University of Michigan School of Public Health. Dr. Agi examines ethnic-racial experiences (e.g., ethnic-racial identity, acculturation, socialization, discrimination) and their implications for youth of color. Her primary line of research investigates the ethnic-racial identity of Black youth with immigrant parents. Dr. Agi will serve as project manager, working with Dr. Zimmerman to develop and implement the the first iteration of the adapted curriculum.

Co-Investigator, Deborah Rivas-Drake, Ph.D., is a Professor in the Department of Psychology, LSA, and School of Education at the University of Michigan. Her research examines how school, peer, family, and community settings support adolescents in navigating issues related to race and ethnicity, and how these experiences inform young people's academic, socioemotional, and civic development. She has served as Principal Investigator for research funded by the National Science Foundation, Private Source. Her book, Below the Surface: Talking with Teens about Race, Ethnicity, and Identity (Princeton University Press), received the Social Policy Book Award from the Society for Research on Adolescence and the Eleanor Maccoby Award in Developmental Psychology from the American Psychological Association. She is a former Associate Editor of Developmental Psychology and Cultural Diversity and Ethnic Minority Psychology and Consulting Editor of Child Development. She will provide expertise in racism, ethnic-racial identity, and adolescent development and will help guide the development and adaptation of the curriculum, outcomes assessment, and data analysis.

Co-Investigator, Enrique Neblett, Jr. Ph.D., is a Professor in the Department of Health Behavior and Health Education in the University of Michigan School of Public Health. Dr. Neblett's research examines the link between racism and health in African American youth, and he has published articles in clinical, developmental, biological, applied, and multidisciplinary psychology outlets such American Psychologist, the Journal of Clinical Child & Adolescent Psychology, Child Development, Cultural Diversity & Ethnic Minority Psychology (CDEMP), Psychophysiology, Psychosomatic Medicine, Health Psychology, and the Journal of Black Psychology. He also has served as the Principal Investigator for several studies funded by the National Science Foundation (NSF), the National Institutes of Health, and the Private Source. In addition to his research accomplishments, Dr. Neblett teaches courses on psychological disorders of childhood and adolescence, African American psychology, racism, racial identity, and African American mental health, and intersectionality. Dr. Neblett is an Associate Editor for CDEMP and also sits on the Editorial Board for the Journal of Black Psychology. He will provide expertise in racism, racial identity and adolescence, and will help guide the development and adaptation of the curriculum, and the outcomes assessment and data analysis.

Co-Investigator, Riana Anderson, Ph.D., is an Assistant Professor in the Department of Health Behavior and Health Education at the University of Michigan School Of Public Health. Dr, Anderson uses mixed methods in clinical interventions to study racial discrimination and socialization in Black families to reduce racial stress and trauma and improve psychological well-being and family functioning. She investigates how protective familial mechanisms such as parenting and racial socialization operate in the face of risks linked to poverty, discrimination, and residential environment. She has recently developed a five-session intervention entitled EMBRace (Engaging, Managing, and Bonding through Race) to alleviate racial stress and trauma in parents and adolescents in order to facilitate healthy parent-child relationships, parent and adolescent psychological well-being, and healthy coping strategies. Dr. Anderson will provide expertise and guidance in relation to anti-racism and cultural equity and help guide the adaptation and implementation of the YES E-RACE curriculum. She will assist the final development of outcome measures and research protocols and participate in data analyses, presentations and publications.

Co-Investigator, Hsing-Fang Hsieh, Ph.D., is Research Investigator in the Department of Health Behavior and Health Education in the UM School of Public Health. She is the project director for the University of Michigan Flint Adolescent Study, a 20 year longitudinal study of youth growing up in Flint, MI and Co-PI for the NIJ funded Sandy Hook Promise Foundation school safety initiative evaluation. Her research focuses on adolescent resilience, youth violence and violence victimization and has expertise in longitudinal and cross-domain data analysis. Dr. Hsieh will coordinate the implementation evaluation and provide leadership to the project staff on recruitment, data collection and analyses, reporting and dissemination activities.

Co-Investigator, Kelley Kidwell, Ph.D., is a Research Associate Professor of Biostatistics. Dr. Kidwell has been a member of the Biostatistics, Analytics and Bioinformatics Shared Resource since 2012 and lead statistician of the Research Development Core at the Michigan Institute for Clinical and Health Research (MICHR; our Clinical and Translational Science Award unit) since 2014. Her research centers on the design and analysis of clinical trials, especially sequential multiple assignment randomized trials. Dr. Kidwell will serve as a co-investigator on this project to oversee the statistical design and analysis of the proposed trial.

Co-Investigator, Sarah Stoddard, Ph.D., is an Assistant Professor in the UM School of Nursing. Her research focuses on understanding the interaction between individual factors and social and environmental factors, and how together they shape the psychosocial development and health trajectories of at-risk urban youth. Dr. Stoddard is currently leading an adaptation for the YES program for Future Orientation. Dr. Stoddard will assist in developing measures, participate on the implementation and adaptation of the curriculum. She will also participate in the data analyses and preparation of presentations and publications.

Project Director, Alison Grodzinski, MLIS, is a Research Area Specialist Senior at the UMSPH and serves as Managing Director for the CDC-funded Prevention Research Center of Michigan and Michigan Youth Violence Prevention Center and the BJA funded National Center for School Safety. Ms. Grodzinski has a Masters of Library and Information Sciences and a Graduate Certificate in Public Health. She will assist PI Zimmerman with oversight of the project, to ensure deadlines are met, and supervise research staff. She will assist with monitoring contract and budget compliance, and developing project publications, reports and communications materials. She will also participate in the development of the YES ERace curriculum and assist with teacher training and implementation tracking. She will provide support for research reports, publications and communication materials.

Rachel Wyatt, BS, Data Manager. Ms Wyatt is the Data Manger for the Prevention Research Center of Michigan. She will work with the research staff and co-investigators to develop and implement a protocol for cleaning and managing the data collected from the schools. She will set up the data for analysis and assist with analyses.

Web Administrator, Joe Alberts. Mr. Alberts is the web administrator for the Michigan Youth Violence Prevention Center and YES project. He will provide support for communications and dissemination for the project including, curriculum design and formatting, printing and creating online dissemination tools for the final products. He will also provide technical support to researchers and project managers for data collection, management and product tracking.

Research Secretary, Ardele Stewart. This project will require an extensive amount of administrative support, which is significantly greater than the routine level of such services provided by academic departments, because it involves data collection and intervention delivery and multiple purchase of service contracts. The Research Secretary will handle contracts with the schools, monitor and process payments and purchases necessary for implementing the interventions. She will provide support for the research staff including preparing project materials, process expense reports, scheduling meetings, maintaining research records and databases, ordering project supplies, and preparing meeting notes.

Research Specialist, Susan Franzen, MA. Ms. Franzen is a research specialist located in Flint, MI. Ms. Franzen has worked with the YES program since 2008. She will coordinate and provide training and technical assistance for the school administrators and teachers carrying out the YES program. She will assist in curriculum adaptation and pilot testing and will be responsible for data management and for supervising survey and all data collection in schools. She will supervise RAs in the schools and data entry and cleaning and assist with data analyses and publications. She will also assist with qualitative analyses for the implementation study.

AME00117777-We now refer to the program as YES-IDEAS (Youth Empowerment Solutions for Inclusion, Diversity, Equity, Appreciation, and Solidarity) instead of YES ERACE.

5.2* Will the involvement of ANY subjects in this study be limited to analysis of their existing data or specimens?

○ Yes ● **No**

5.3* Will the study involve recruitment and/or participation of subjects in order to produce new data (e.g., surveys, interaction, intervention)? *[Require sections 8-1 and 11-3]*

● **Yes** ○ No

5.4* List the inclusion and exclusion criteria for this study population and/or data set. (If covered in attached protocol, indicate section)

Students enrolled in summer programs at middle schools in six schools in Genesee County Intermediate School District. Students will be in 6th to 8th grade. All students will be included if their guardians consent and they assent

Ame00117777
Students enrolled in afterschool programs at middle schools in six schools in Genesee County Intermediate School District. Students will be in 6th to 8th grade. All students who assent and whose parents do not notify us of their refusal of their student to participate in the study will be allowed to participate.

5.5 Identify any racial, ethnic, or gender group(s) that will be specifically excluded from participation in this research study and provide a compelling justification for such exclusion:

None

5.6* Indicate the age range (in years) of the subject population in this study.

Minimum Age: 10
Maximum Age: 15If no upper limit, enter "999"

View: 06. Benefits and Risks
Section: 06. Benefits and Risks

06. Benefits and Risks

6.1 * Describe the potential benefits of this research to society.

This is a study to assess the effects of the YES intervention supplement as compared to students enrolled only in the summer program. All youth in the school could benefit from an improved school climate and greater understanding of race and improved intergroup relations. We will contribute to scientific knowledge by assessing specifically the affects of including the adapted YES ERACE curriculum in summer school programs. We hope that the results of this study will help to improve future summer programs and foster more positive race relations in schools.

This survey compares two different types of summer programs. We hope to determine which type of program is best for positive youth development and intergroup relations outcomes.

AME00117777- We are conducting the study in the context of an after-school program (rather than summer program).

AME00117777- We now refer to the program as YES-IDEAS rather than YES ERACE.

6.2 * Will results of the research be communicated back to the subjects?

● **Yes** ○ No

6.2.1 * Explain the plan and process.

We will communicate the results of the research to the youth, their parents, and the schools who participate in the project through group meetings and newsletters. We will also communicate the results to the community through oral presentations and written reports. Links to academic presentations and publications based on this research will also be available through the PRC- MI website.

6.3 * Describe any direct risks to the public or community, which could result from this research?

We do no know of any foreseeable risks to the public or community.

6.4 * Does this project involve study arms that have differing levels of benefit or risks to subjects?

○ Yes ● **No**

6.5 * Benefits and Risks:

Click "Add" to begin entering the benefit and risk level detail information associated with this study.

	Name	Risk Level	Direct Benefit
View	HUM00190523	No more than minimal risk	yes

View: Benefits and Risks Detail
Section: 06. Benefits and Risks

Benefits and Risk Level Detail

If a study involves multiple arms or phases that pose different levels of risk or direct benefits to subjects, then create an entry for each arm or phase using the "OK and Add Another" option at the bottom of this page. Only one entry is necessary if the risk level and the direct benefit to subjects is the same for the entire project, even if the study involves multiple arms or phases.

6.5.1 * **Name of Arm (experimental group, study wave, etc.)**

HUM00190523

6.5.2 * **Description of Arm (experimental group, study wave, etc.)**

6.6 * **Are there potential direct benefits of this research to the subjects?**

● **Yes** ○ No

6.6.1 * **Describe the potential direct benefits.**

Students will benefit from the training provided to increase their interpersonal empowerment, interactional empowerment, and behavioral empowerment, which will in turn reduce racial perpetration and victimization.

Student will also learn more about themselves and their community. They may also learn more about research.

Teachers and other adults participating in the project can benefit from the training provided to increase their knowledge of anti-racism curricula. They can also benefit from working with youth to improve intergroup relations.

6.7 * **Provide a description of the foreseeable risks to subjects. For studies involving multiple arms or phases, enter the risks for this arm or phase only.**
Provide a description of the foreseeable risks to the subjects.
For EACH identified risk, include:

- **Likelihood of the risk,**
- **Seriousness to the subject; and**
- **What measures will be taken to minimize the risk (for example, study design includes the substitution of procedures already being performed on the subject for diagnostic or treatment purposes, or in a study of Post-Traumatic Stress Disorder, the investigator takes steps to identify, manage, or refer as appropriate, subjects for whom the study may evoke very difficult emotions)**

If possible, please use the following categories to assess the likelihood:

- **"Common" (i.e., approximate incidence > 25%)**
- **"Likely" (i.e., approximate incidence of 10-25%)**
- **"Infrequent" (i.e., approximate incidence of 1-10%)**
- **"Rare" (i.e., approximate incidence < 1%):**

There are a few risks for students in this study. Some survey questions could be upsetting (infrequent likelihood). The research team will help students who get upset. We will include training for survey administrators to recognize distressed students and have established a protocol that includes referring the student to the school counselor or to community resources as appropriate.

Students might be worried about their privacy. The research team will do everything we can to keep students' answers private. Their names will never appear on the survey forms. They will complete the survey in private. They will place the survey in a sealed envelope before they turn it in. We will train all staff to keep data private. All surveys will be stored in locked cabinets. All data will be stored in locked computers. We also have a Certificate of Confidentiality to keep your data private. But in the very unlikely event (rare) that these privacy protections fail, students might feel ashamed. Students can choose to skip any questions on the survey. All program activities will be run by adult staff or volunteers. To protect students' safety all adults involved must pass background checks.

To protect confidentiality in the case of an accidental breach, all information will be coded so that it cannot be associated with any individual. A separate document with individual names and code numbers will be kept in a locked file cabinet under the direct supervision of the Principal Investigator (PI). All data entered into the computerized database will be identifiable by subject code number only. No one outside of the research team will have access to records identifying subjects' names at any time. The information gathered will be used only for scientific, educational, or instructional purposes.

6.8 * **What is the level of risk of harm to the subjects, resulting from this arm of the research? For studies involving multiple arms or phases, enter the level of risk for this arm or phase only.**

Risk Level	Description

	Risk Level	Description
●	**No more than minimal risk**	**A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination. (Note: The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.) Refer to the Risk Grid for more information.**
○	Minor increase over minimal risk	While this risk category may be used to classify research involving adult subject populations, it must be considered in the evaluation of risk in research involving children as defined in 45 CFR 46 sections 404-407*** Risks are more severe than those defined as “No more than minimal risk” and less severe than those described as “Moderate” on the Risk Grid.
○	Moderate risk	Refer to the Risk Grid for more information.
○	High risk	Requires scrutiny in regards to the likelihood of direct benefits, and whether or not benefits clearly outweigh risks. Refer to the Risk Grid for more information.

6.9 * Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits.

This study involves minimal risk. Participants will be asked about their thoughts, attitudes, and behaviors, which might be upsetting for some youth. We will include training for survey administrators to recognize distressed students and have established a protocol that includes referring the student to the school counselor or to community resources as appropriate.

This minimal risk is reasonable in relation to the benefits. We have mitigated the possible outcomes to minimize distress.

View: 07. Special Considerations
Section: 07. Special Considerations

07. Special Considerations

7.1* Does this study involve human tissue or biological specimens (use, collection, or secondary analysis) (e.g. blood, urine, bone marrow, skin, etc.)? [Require Section 18]

○ Yes ● **No**

7.2* Does this study involve the secondary analysis **of a** pre-existing data set**, including data associated with any specimens identified in response to question 7.1? [Require Section 24]**

○ Yes ● **No**

7.3* Will the research involve the access, collection, use, maintenance, or disclosure of protected health information (PHI)? PHI is:

- **information about a subject's past, present, or future physical or mental health, the provision of healthcare to a subject, or payment for the provision of healthcare to a subject; AND**
- **maintained by a HIPAA-covered entity (e.g. healthcare provider, healthcare plan, or healthcare clearinghouse).**

[Require Section 25]

○ Yes ● **No**

View: 07-1. Special Considerations - Continued
Section: 07. Special Considerations

07-1. Special Considerations - Continued

7-1.1* Will subjects receive payment or other incentives for their participation in the study? [Require Section 13]

● **Yes** ○ No

7-1.2* Will subjects undergo healthcare-related treatments or procedures (standard of care and/or research) as part of the study? [Require Section 14]

○ Yes ● **No**

7-1.3* Does this study involve the deception **or concealment of subjects? [Require Section 27]**

○ Yes ● **No**

7-1.4* Excluding routine email correspondence, does this study involve the use of the Internet or email as an integral part of the research design or will sensitive information be transmitted by e-mail? [Require Section 28]

○ Yes ● **No**

7-1.5* Will the study collect data using surveys, interviews, or focus groups? [Require Section 29]

● **Yes** ○ No

7-1.6* Does this study require subjects to listen to an audio recording or view images? [Require Section 31]

○ Yes ● **No**

7-1.7* Will any drugs, biologics, radiopharmaceuticals, nutritional (e.g., herbal or alternative medication) supplements or other material be administered, implanted, or applied to the subjects as the object of the study? [Require Section 15]

○ Yes ● **No**

7-1.8* Will the study involve a placebo (drug, device, procedure, intervention, surgery, etc.) control group? [Require Section 17]

● **Yes** ○ No

7-1.8.1* Is the placebo for a drug? [Require Section 15]

○ Yes ● **No**

7-1.9* Will the study involve human embryonic stem cells (hESCs) or induced pluripotent stem cells? [Require Section 19]

○ Yes ● **No**

7-1.10* Will the study have a Data and Safety Monitoring Plan (DSMP)? [Require Section 32]

● **Yes** ○ No

View: 07-2. Special Consideration - Continued
Section: 07. Special Considerations

7-2. Special Consideration - Continued

7-2.1* Will any devices be used, administered, implanted, or applied to the subjects, or will human specimens be used to test in vitro diagnostic devices? [IRBMED Applications Require Section 16]

○ Yes ● **No**

7-2.2* Is the research testing or utilizing a health-related mobile software application that is:

- Designed for a handheld (e.g., smartphone) or wearable mobile device (e.g., exercise tracking), or
- Tailored to a mobile platform (i.e., a handheld commercial or off-the-shelf computing platform, with or without wireless connectivity) but executed (run) from a server

and the mobile software application/platform performs any of the following:

- Uses a built-in feature of a device such as light, vibration, or camera to perform a medical device function.
- Connects or links to an existing device to control its operation, function, or energy source.
- Uses patient-specific data from a connected device including a sensor or electrode to monitor, manipulate, calculate, or analyze information.
- Conveys diagnostic information, or provides education materials or encouragement.
- Performs calculations, conversions, measurements or interpretations.

○ Yes ● **No**

7-2.3* Will the subjects be exposed to any ionizing radiation during the course of this study? [Require Section 21]

○ Yes ● **No**

7-2.4* Will any organs, tissues, or cells from humans (including fetal tissue) or animals be administered to the subjects for the purposes of this study? [Require Section 22]

○ Yes ● **No**

7-2.5* Does this study involve a gene transfer intervention or an intervention based on recombinant DNA technology? [Require Section 23]

○ Yes ● **No**

View: 08. Subject Participation
Section: 08. Subject Detail

08. Subject Participation

8.1* Please indicate the number of subjects to be enrolled from ALL study locations to achieve the goal of the study:

410

8.2* Enter the estimated number of subjects to be enrolled at each University of Michigan site:

Location or Institution	Total	
Genesee Intermediate School District		
Adults		
Children		
University of Michigan		
Adults	0	
Children	410	
Total from all University of Michigan sites:		**410**

View: 08-1. Subject Recruitment
Section: 08. Subject Detail

08-1. Subject Recruitment

8-1.1* At what point in the study are you planning on beginning the recruitment of subjects?

0-2 years after approval

8-1.2* Indicate which of the following established subject pools, if any, will be used for recruitment.

Select all that apply:

Children at their preschool, elementary, middle, or high school location

Provide Related UM IRB Project Number or Subject Pool Description:

8-1.3* Describe the manner in which potential study subjects will be recruited. List how, when, who will recruit and where they will be recruited. Include any provisions to protect or maintain subject privacy.

We will recruit 6th to 8th graders from six middle schools identified by the GISD superintendent. Parents will be contact for consent for their child to participate in the study after the child has signed up for their summer program. Students will be recruited to participate if their parent has consented, prior to the start of the summer program. Parent/guardian consent for student participation in the intervention and all assessments will be obtained at the time of recruitment by sending letters home in the summer programming announcement packet sent out by schools. The letters will include information about the study and procedures for returning signed consent. We will follow up this mailing by calling parents who have signed their child up for the summer. We will also hold study orientation meetings for parents at the six schools (to coincide with other parent-school activities), attend spring events at schools, and advertise the study in school mailings so we have multiple methods of informing students and their families about the study. Students whose parents have consented to their participation will assent during each survey collection.

Ame00117777 Parent/guardians will be sent a letters home in the after school programming announcement packet sent out by schools. The letters will include information about the study and procedures for how a parent can refuset. We will follow up this mailing by calling parents who have signed their child up for the after school program. We will also hold study orientation meetings for parents at the six schools (to coincide with other parent-school activities), attend fall events at schools, and advertise the study in school mailings so we have multiple methods of informing students and their families about the study. Students whose parents have provided passive consent to their participation will provide assent.

8-1.3.1 If applicable, how will prospective subjects' healthcare providers (e.g., physician, dentist, etc.) be involved in the recruitment and/or be notified of their individual patients' participation in the study?

N/A

8-1.4* Explain how the recruitment strategy is equitable and represents the population required for the study. If the information is covered in the attached protocol, please indicate section.

Schools will be selected based on their population being representative of the community. After the six schools are identified, we will randomly assign schools to either the intervention or the control. Based on guidelines from the CONSORT Group, sample information to be assessed at the end of the study will include 1) number of youth in the summer program (i.e., eligible), 2) number of families completing consents, assents, and baseline assessments, 4) number of youth receiving the YES-ERACE or usual summer program, and 5), number of youth lost to follow-up. We will conduct attrition analyses to assess group differences.

Ame00117777
These program will tale place afterschool. Schools will be selected based on their population being representative of the community. After the six schools are identified, we will match them on size and demographics and free lunch data. When possible we will randomly assign schools to either the intervention or the control. Based on guidelines from the CONSORT Group, sample information to be assessed at the end of the study will include 1) number of youth in the summer program (i.e., eligible), 2) number of families completing consents, assents, and baseline assessments, 4) number of youth receiving the YES-ERACE or usual afterschool program, and 5), number of youth lost to follow-up. We will conduct attrition analyses to assess group differences

8-1.5* Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their initial enrollment into the study?

● **Yes** ○ No

8-1.5.1* Describe how frequently and in what manner individuals will be contacted. If the information is covered in the attached protocol, please indicate section.

We will send letters to parents and follow-up by email. We will also hold study orientation meetings for parents at the six schools (to coincide with other parent-school activities), attend spring events at schools, and advertise the study in school mailings.

Ame00117777
GISD will send letters to parents.. We will also hold study orientation meetings for parents at the six schools (to coincide with other parent-school activities), attend events at schools, and , if available, GISD will advertise the study in school mailings.

8-1.6* Indicate which methods will be used for recruitment?

Check all that apply:

- Face-to-face contact (e.g. during a health care visit or an interview at a home address, etc.)
- Email
- Postal mail
- Letter/flyer distributed through intermediary organization (e.g. schools, churches, clubs, etc.)

If other please specify:

8-1.7 How will any email, address, and/or telephone lists be obtained?

E-mail addresses will be provided by the child or the parent that expressed an interest in the study. The schools will partner with each of the six schools to print mailing labels based on most up to date information about student addresses held by the schools.

8-1.8* What materials will be used for recruitment? The IRB must approve all recruitment materials.

See Help for important information regarding the requirements for recruitment materials

Check all that apply:

- Oral scripts
- Email messages
- Letters/postal mail

If other please specify:

If Web pages will be used, provide the Web address (URL) for the location where the pages will be posted (also upload the content of the pages below):

Upload recruitment materials here:

See Help for more information about working with documents (e.g. uploading, downloading, and editing).

Name	Version
AME00113396 ProgramDevEval_ Child Recruitment Script 7.2.21.docx(0.04)	0.04
AME00113396 ProgramDevEval_Parent Recruitment Letter 6.27.21.docx(0.02)	0.02
AME00114207_Cover letter for YES parent consent.docx(0.01)	0.01
AME0011777 GISD Recruitment Letter clean copyv12.16.21.docx(0.04)	0.04
Email invitation for parents(0.01)	0.01
Email reminder for parents(0.01)	0.01
Recruitment Script(0.01)	0.01

☐ **Check here if any of the materials are not available electronically.**

Note: Study Teams are encouraged to scan and upload documents. See Help for a list of sites with scanning facilities

View: 09. Survey Populations
Section: 09. Subject Populations

09. Survey Populations

9.1* Is the study limited to a survey of either:

- The general adult population (aged 18 or older); or
- A subgroup of the general population which does not specifically target:

- Pregnant women and/or fetuses
- Lactating women
- Women of child-bearing potential
- Prisoners
- Cognitively impaired adults
- College students
- Economically or educationally disadvantaged persons
- Patients of the study team
- Employees, students or trainees of the study team
- Family members of the study team

where the survey is the sole interaction with the subject and does not pose more than minimal risk?

○ Yes ● **No**

View: 09-1. Subject Populations
Section: 09. Subject Populations

09-1. Subject Populations

9-1.1* **Is the research designed to include or allow the following populations?**

Select all that apply

- [ ] **Normal, healthy subjects**
- [ ] **Adults** *age 18 and older*
- [ ] **Minors able to consent** *to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (e.g. emancipated minors or minors seeking treatment for certain conditions.)*
- [x] **Children and/or Viable Neonates** *(i.e. persons who have not yet reached the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted) [Require Sections 33 and 41]*
- [ ] **Neonates of uncertain viability and/or nonviable neonates** (do not check this box if the research is solely retrospective. For retrospective research regarding neonates of uncertain viability, check the box for 'Children'. See Help for additional information.) [Require Section 34]
- [ ] **Individuals and/or products involving human in vitro fertilization**
- [ ] **Pregnant women and/or fetuses** [Require Sections 35 and 41]
- [ ] **Lactating women** [Require Section 36]
- [ ] **Women of child-bearing potential** [Require Section 37]
- [ ] **Prisoners** (If the research includes a study population that is likely to become incarcerated during the conduct of the research, also select this category) [Require Section 38 and 41]
- [ ] **Cognitively impaired adults** [Require Sections 39 and 41]
- [ ] **College students** [Require Sections 40 and 41]
- [ ] **Economically or educationally disadvantaged persons** [Require Section 41]
- [ ] **Patients of the study team** [Require Section 41]
- [ ] **Employees, students or trainees of the study team** [Require Section 41]
- [ ] **Family members of the study team** [Require Section 41]
- [ ] **Unknown, unspecified population**

View: 10. Informed Assent - Children
Section: 10. Informed Consent

10. Informed Assent - Children

10.2* What types of informed assent for children and parental consent/permission will be obtained?
NOTE "Parent" or "Parental" below refers to parent or guardian. See Help **for important instructions on selecting the appropriate category or categories.**

Children
With signature:

- [x] **Written document**

Without signature (waiver of documentation):

- [ ] Written document
- [ ] Oral assent script

Waiver of assent:

- [ ] Request for waiver of informed assent

Other:

- [ ] Pre-existing assent covers this activity

Parents
With signature:

- [ ] Comprehensive written

Without signature (waiver of documentation):

- [ ] Comprehensive written
- [ ] Comprehensive oral consent/permission script

Waiver of parental consent/permission:

- [x] **Request for waiver of parental consent/permission (Note: no longer required for screening/recruitment)**

Other:

- [ ] Short form permission, comprehensive oral script, and witness
- [ ] Request to use substitute mechanism for parental permission where research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects
- [ ] Request for IRB to appoint an advocate for children who are wards of the state or any other agency, institution or entity – required for studies related to the children's status as wards that are approved under 46.406 or 46.407 (see section 33)
- [ ] Pre-existing consent/permission covers this activity

10.2.2* Describe the process to seek and obtain informed assent for children and parental consent/permission (e.g., setting, timing, personnel involved, arrangements for answering subject questions before and after the consent is signed).

We will use multiple methods of informing parents and students about the study. Once a child or parent has expressed an interest in the study, we will give a parent consent form to the interested parent or child. The consent form will have a phone number of the Project Director, a U of M staff member if parents want to call and have questions answered before signing the consent form. Parents and children can return their forms to program staff.

All students interested in enrolling in the study and who have a returned and signed parent consent form, will be invited to read and sign an assent form. A member of the UM research team, the summer program Site Coordinator or a member of the summer program staff will distribute the assent forms to the students. The students will be told that they can ask questions about the contents of the assent forms before they sign the forms.

The assent forms will be read and signed immediately before the students complete the first (baseline) survey. The students will be asked to read the assent form on their own unless they wish to have someone read the assent form read to them. The assent form will be written at a 5th grade reading level.

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Each participating school/school district would agree to passive parental consent. Letters about the study will be sent home in regular mailings from GISD to the parents
of all students enrolled in the GISD afterschool programs in the 6 participating schools. The letter will contain details about the study and information about the program and the program evaluation study including the usual information required by a parent consent along with contact information for the U of M research team for parents to call/email if they DO NOT want their child to be involved with the evaluation study. The letter will also include how to exclude their children from photographs.

Students will still participate in the program as that will be what is being offered for afterschool for that particular cluster (8 week period), but they will not participate in the data collection if a parent contacts

the research team to remove their child from the study. We will obtain written youth consent. U of M research team members will collect the evaluation data. We will also collect data at four timepoints: pretest, immediate posttest, and 6 and 12 months after completion of the program. Students' surveys will be labeled with their unique student ID number (not their name). We will keep a file with students' names linked to their ID numbers separately on a secure (password protected) drive. No student names will ever appear on the surveys. Only study team members will have access to the linking file. The linking file will be deleted from the drive at the conclusion of the study.

U of M Staff will assent the children at the school The assent forms will be read and signed immediately before the students complete the first (baseline) survey. The students will be asked to read the assent form on their own unless they wish to have someone read the assent form read to them. The assent form will be written at a 6th grade or below reading level.

10.2.3* What criteria will be used to determine whether or not a child's assent to participate will be obtained, whether that assent will be oral or written, and whether documentation of the child's assent (e.g., signature on the assent form) will be obtained? If documentation of child's assent is to be waived, provide a justification.

All children participating in the study will assent. Children will sign a written assent.

10.2.4* Are any of the following changes expected in the status of child subjects during the study?

Check all that apply:

Expect no change in status of child subjects

10.2.4.1 If applicable, describe the plan to re-assent or obtain consent from the subject if any of the changes occur.

N/A

View: 10-1. Informed Consent
Section: 10. Informed Consent

10-1. Informed Consent

10-1.1* All documents related to consent, assent, permission, and or debriefing documents, including oral scripts must be uploaded here. If you are requesting a waiver of documentation of informed consent, upload a copy of any written materials to be provided to participants, and provide a written description of any information to be provided orally.

Name	Version
AME00113396 ProgramDevEval_ Child Assent 7.1.21.docx(0.02)	0.02
AME00113396 ProgramDevEval_ Parent Consent 7.1.21.docx(0.02)	0.02
AME00117777 YES-IDEAS Child Assent FINAL 12.16.21 Clean Copy.docx(0.04)	0.04
AME00117777 YES-IDEAS Parent OPT OUT information Clean Copy _1.10.22.docx(0.03)	0.03
ERACE Child Assent 4.30.21(0.05)	0.05
ERACE Parent Consent 4.30.21(0.09)	0.09

10-1.2* Will the subjects be audiotaped, videotaped, or photographed (identifiable images of subject) during the research?

○ Yes ● **No**

10-1.3* Is there a substantial likelihood that the research will be conducted among a non-English-speaking population?

○ Yes ● **No**

10-1.4* Indicate which anticipated costs could be the full or partial responsibility of the subject.

Check all that apply:

No anticipated costs

If other, please specify:

10-1.5* Is the study designed to collect identifiable information from primary research subjects about other individuals, including family members?

○ Yes ● **No**

10-1.6* At the conclusion of this study, will specimens and/or data be retained for future research use?

● **Yes** ○ No

10-1.7* Does the informed consent document explicitly notify subjects that their data and/or specimens will be stored for future research?

● **Yes** ○ No

10-1.8* Are subjects required to agree to retention of their data and/or specimens as a condition of participating in the research?

○ Yes ● **No**

View: 10-3. Informed Consent Waiver
Section: 10. Informed Consent

10-3. Informed Consent Waiver

10-3.1* This request is for:

Select all that apply:

Alteration to required element(s) - General - PART of the project

10-3.1.1 If this request is for PART of the project, identify the specific research procedures (e.g., screening interview) and/or the specific subject populations (e.g., parents of child-subjects) involved.

Ame00117777
This is request is for parent passive consent. Children will be assented

10-3.1.2 Explain any requested alterations to the informed consent process.

Ame00117777
Each participating school/school district would agree to passive parental consent.Letters about the study will be sent home in regular mailings from GISD to the parentsof all students enrolled in the GISD afterschool programs in the 6 participating schools.
The letter would also include a passive parental Consent form, including the usualparent consent information along with contact information for the U of M research teamfor parents to call/email if they DO NOT want their child to be involved with theevaluation study. Students will still participate in the program as that will be what isbeing offered for that particular cluster (12 week period), but they will not participate inthe data collection if a parent contacts the research team to remove their child from thestudy. We will obtain written youth consent. U of M research team members will collectthe evaluation data. We will also collect data at four time points: pretest, immediateposttest, and 6 and 12 months after completion of the program. No questionnaire (electronic or paper) will ever have the child's name associated with it and their writtenconsent will be stored separately and not be linked to the questionnaire data.

10-3.2* Check below to affirm that this study meets each of the criteria for waiver or alteration of informed consent and explain how:

☑ (i) The research involves no more than minimal risk to the subjects.

Explain
Ame00117777
The research involves no more than minimal risk to the subjects. With the exception of demographic questions for participants, the questions are about Knowledge, beliefs, attitudes or behaviors that might be affected by the GISD program.

☑ (ii) Research could not practicably (i.e., feasibly) be carried out without the waiver or alteration.

Explain
Ame00117777
During our pilot, we learned that parents not returningsigned consent forms to the school was a barrier to meeting our enrollment goals andwe were at a much smaller scale of participants than during full implementation Thus, we are concerned that our ability to achieve study recruitment goals especially duringthe continuing effects of COVID-19 will be significantly hampered,

☑ (iii) If the research involves identifiable private information or biospecimens, the research could not be practicably carried out without using such information or biospecimens in an identifiable format.

Explain
Ame00117777
We need to track students across time to look at individual outcomes. All students will have a linking ID number. The personal data will be stored on the secure drive in a separate folder from the data.

☑ (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects.

Explain
Ame00117777
Students will sign assent forms. Parents can remove their child from the study at any time if they so desire. The study is also protected by the Certiicate of Confidentiality

☑ (v) Whenever appropriate, the subjects or their Legally Authorized Representative will be provided with additional pertinent information after participation.

Explain
Ame00117777
Parents will be sent a letter at the beginning of the study. If there is any pertinent information to provide, the study manager will contact the parents by phone, email or letter.

View: 11. Confidentiality/Security/Privacy
Section: 11. Confidentiality, Security and Privacy

11. Confidentiality/Security/Privacy

11.1* Will the study team access any data that is linked to a subject's identity by name or other identifier or code? [Require Section 11-1]

● Yes ○ No

11.2* Explain how the subjects' privacy will be protected.

Participants will complete the first two surveys at the start and end of summer program, in their summer program classroom. We will train staff to keep all data private. Each participant will complete their survey privately and place completed surveys in sealed envelopes before submitting the surveys to the research staff. Only research staff will have access to the completed surveys. Follow-up surveys will be completed by participants. Participants will be asked to find a private place where they can complete the follow-up surveys. We will give participants the option of completing the survey on Qualtrics, which can be done from the privacy of their own phone.

A document with individual names and code numbers will be kept in a locked file cabinet under the direct supervision of the Principal Investigator (PI). Surveys will be kept in a separate locked file cabinet. All data entered into the computerized database will be identifiable by subject code number only. No one outside of the research team will have access to records identifying subjects' names at any time. We will destroy hard copies of the questionnaire once the data have been entered into the computerized database and checked for accuracy.

11.3* How will the study team protect research records, data, and/or specimens against inappropriate use or disclosure, or malicious or accidental loss or destruction in order to protect the confidentiality of subject data?

Select all that apply:
Locked office
Locked cabinet or storage unit
Restricted access
Restrictions on copying study-related materials
Access rights terminated when authorized users leave the project or unit
Individual ID plus password protection
Routine electronic back up
No non-UM devices are used to access project data, or any that are used to access project data use secure connections to communicate with U-M services (e.g. VPN – “virtual private network”)
Security software (firewall, anti-virus, anti-intrusion) is installed and regularly updated on all servers, workstations, laptops, and other devices used in the project
Safe disposition/destruction of data or devices, as appropriate (e.g., shredding paper documents, destroying disks or thumb drives, secure erasure of electronic media)
Other

If other please specify:
Data Safeguards
All data will be stored on a password protected server at the University of Michigan School of Public health. The files are firewalled in a number of ways by both the University and School, files are accessible only by password protected accounts, and files will only be accessible to research staff approved by the PI. Only research staff and faculty members will have access to files containing subject data. All information linking participant identification numbers with specific individuals will be kept in a separate locked file cabinet under the direct supervision of the PI. All identifying information with the exception of the subject identification number will be removed from the data. No information about the identities of study participants will be published or presented at conferences or other public meetings.

11.4* Does either statement apply to this research:

Research has NIH, CDC, or FDA funding, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award:

The study will include identifiable sensitive information, identifiable biospecimens, individual human-level genomic data/biospecimens, or any information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

or

Research does NOT have NIH, CDC, or FDA funding, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award:

The study will include identifiable, sensitive information or identifiable biospecimens that, if revealed, might place the subjects at risk for personal safety, criminal or civil liability, or damage to their financial standing, employability, insurability, or reputation.

[Require Section 11-2]

● **Yes** ○ No

11.5* Will data be provided to a repository as part of a data sharing agreement?

○ Yes ● **No**

11.6* What will happen to the data and/or any specimens at the conclusion of this study?

Select all that apply:
Retain for study recordkeeping purposes
Retain for future research use - requires Section 11-4

11.6.2* If the data and/or specimens will be retained for study recordkeeping purposes, provide the following information (if covered in the attached protocol, please indicate section):

- expected duration of the retention period,
- any changes in the conditions or arrangements for storage of research data/specimens during the retention period, if different from those listed above in question 11.3.

We will retain the paper subject data files. After four years after study completion (2029) the subject data (i.e. paper documents) will be shredded. The data files will continue to be stored for future use as identified above.

View: 11-1. Identifiable Data
Section: 11. Confidentiality, Security and Privacy

11-1. Identifiable Data

Completion of this section is required based on the response provided to question 11.1.

11-1.1* Indicate how subjects are identified in the research records.

Select all that apply:

Coded or Indirect Identifiers - data record includes a link to direct identifiers (e.g., name, initials, phone number, SSN, or medical record number linked to data record but stored separately)

11-1.2* Explain the necessity for collecting or maintaining data linked to subjects' identities. If the information is covered in the attached protocol, please indicate section.

We need to maintain subject contact information for follow up and payment of their incentives for completing questionnaires. Participant information will be kept in a separate location from their data, in a password protected file on a computer (not on the network server).

11-1.3* How long will the identifiers be retained?

Identifiers will be destroyed after the last round of incentives have been distributed, within 6 months.

11-1.4* Will individually identifiable sensitive data be accessed, collected, used, maintained, or disclosed in the study?

● **Yes** ○ No

11-1.4.1* Will a continuous, periodic, or automatic feed of sensitive data be set up to provide data directly from any University information system (e.g., M-Pathways, U-M Data Warehouse, CareWeb)?

○ Yes ● **No**

11-1.4.2* Will sensitive data be accessed by individuals who are not University employees?

○ Yes ● **No**

11-1.4.3* Will sensitive data be stored on or accessed from computer equipment that is not maintained and supported by a University IT services provider (e.g., ITS, MCIT, MSIS) - such as home computers, grant-funded computers, etc.?

○ Yes ● **No**

11-1.4.4* Will sensitive data be stored on portable devices (e.g., laptops, PDAs, flash drives) in unencrypted form?

○ Yes ● **No**

View: 11-2. Certificate of Confidentiality
Section: 11. Confidentiality, Security and Privacy

11-2. Certificate of Confidentiality

Completion of this section is required based on the response provided in Section 11

11-2.1* Is there a Certificate of Confidentiality (CoC), or will one be obtained, for this research? (If NIH, CDC, FDA, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award, answer "Yes")

● **Yes** ○ No

11-2.1.1* Select the answer that applies to your CoC:

I will rely on a CoC that is included as part of current NIH, CDC, FDA, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award

View: 11-3. End of Subject Participation
Section: 11. Confidentiality, Security and Privacy

11-3. End of Subject Participation

11-3.1* What specific criteria will be used to prematurely end a particular subject's participation in the study (If covered in attached protocol or informed consent, indicate specific location).

Participants may end their participation in the study at any time. Individuals who desire to be eliminated from the study may contact the research staff at the phone numbers provided to them within the consent process. Any adverse events will be immediately reported to the IRB, and all study activities will halt pending IRB review and recommendations.

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Participants may end their participation in the study at any time. Individuals who wish to be eliminated from the study or parents who wish their child to be eliminated from the study, may contact the research staff at the phone numbers provided to them within the consent process.

Any adverse events will be immediately reported to the IRB, and all study activities will halt pending IRB review and recommendations.

11-3.2* If a participant withdraws from the research, what is the plan to use, disclose, store, or destroy the participant's data and/or specimen?

If a participant withdraws from research, all data collected during the study will be immediately destroyed and will not be used for subsequent analysis.

View: 11-4. Retention of Data and/or Specimens Detail
Section: 11. Confidentiality, Security and Privacy

11-4. Retention of Data and/or Specimens Detail

Retention may be for future research by the investigator and/or the creation of a bank or repository.

Completion of this section is required based on the response provided to question 11.6.

11-4.1* What is the intent or purpose of retaining the data and/or specimens?

Data will be retained for future analysis and for comparison with future studies.

11-4.2* Where will you store the data and/or specimens?

Only at the University of Michigan

If Other Institutions, please specify:

11-4.3* Describe the arrangements for the storage conditions, management, and security of the data and/or specimens. Include the following as applicable:

- ***Personnel access to data and/or specimens***
- ***Whether identifiers will be removed and the key to any code destroyed***
- ***For coded data and/or specimens, indicate who holds key to the code and where it is stored in relation to the data and/or specimens***
- ***Storage plan***
- ***Plan to protect privacy in transfer to other collaborators.***

All data will be stored on a password protected servers at the University of Michigan School of Public health. The files are firewalled in a number of ways by both the University and School, files are accessible only by password protected accounts, and files will only be accessible to research staff approved by the PI. Only research staff and faculty members will have access to files containing subject data. All information linking participant identification numbers with specific individuals will be kept in a separate locked file cabinet under the direct supervision of the PI. All identifying information with the exception of the subject identification number will be removed from the data. No information about the identities of study participants will be published or presented at conferences or other public meetings.
Data security safeguards at the School of Public Health:

* Data are stored on the departmental file servers, with access provided only to people specifically designated by the PI, and to the administrators of the file servers.
* The servers reside in a well protected data center external to SPH, with restricted access requiring use of unmarked entry cards and retinal scanners.
* System hardening settings have been implemented on the storage servers (running Windows 2008)
* In order to access the data, the authorized individuals will have to be connected directly to our LAN, or use a secure VPN connection.
* The data files are backed up daily to an automated backup system maintained by IT Central Services. If needed, specific volumes can be excluded from backup.
* Our network and the servers are protected with a centrally-run firewall service
* Strong passwords are enforced for all user accounts with access to our departmental servers

View: 13. Subject Payments Or Other Incentives
Section: 13. Subject Payments Or Other Incentives

13. Subject Payments Or Other Incentives

Completion of this section is required based on the response provided to question 7-1.1 or 7-3.3.

13.1* Indicate all payments or other incentives provided to subjects for their participation in this study:

Select all that apply:

Cash

HSIP Issued Gift Card

Token gift

If other, please specify:

13.2* If the subject is a child (under the age of majority), are any of the payments or incentives intended for the parent/guardian of the child?

No

13.3* Estimate the maximum total payment (including cash, checks, gift cards, and other cash-equivalent incentives) that an individual subject could receive for participating in this research in a single calendar year.

$26-$100

13.3.1* Please indicate what information you will be collecting from subjects in order to distribute their incentive or compensation.

Select all that apply:

Name

Address

Email

13.4* Describe the frequency of the payments or incentives. If applicable, list any healthcare procedure(s) that will be provided to subjects at no charge.

We will use a graduated incentive structure to enhance youth participation. All participants will be given financial incentives to complete questionnaires, with incentives increasing for each additional assessment ($5 for Pretest, $10 for immediate post-test, $15 for completing Fall post-test, and $20 for completing Spring post-test). Participants who complete all study waves will also be entered in a drawing for a $50-$100 gift certificate at a local mall (multiple prizes will be available). Participants who fail to complete consecutive assessments will still receive the larger incentives to complete later assessments given the value of these data points to test longitudinal hypotheses, but they would not be eligible for the bonus prizes. Bonus prizes will be delivered in the year following the intervention.

13.5* What is the justification for offering these payments or incentives?

To enhance youth participation so that we can test longitudinal hypotheses.

13.6* What is the plan to compensate subjects withdrawing from the research prior to completing the entire study.

We will obtain address, phone, and email information for three people who could reach participants if they move. We will also employ multiple contact strategies during the school year, including phone calls, text messages, emails, and personal contact at schools. School year post-tests will be collected via the web so that data collection does not interfere with school and students can complete the questionnaire at a time convenient for them. For participants who withdraw from the study, they will be compensated for the surveys they participated in.

View: 17. Placebo
Section: 17. Placebo

17. Placebo

Completion of this section is required based on the response provided to question 7-1.8 or 7-3.6.

17.1* Briefly describe the placebo (drug, device, procedure, intervention, surgery, etc.) control arm used in the study.

The control group will be participants enrolled in GISD's regular summer program.

17.2* Provide a justification for use of the placebo, including the length of subject participation in the placebo arm.

The control group will serve as a comparison to YES-ERACE. The summer program is expected to be 4 hours a day, 4 days a week, for 6 weeks.

17.3* Describe any commonly used diagnostic/treatment approach(es) that will be withheld from subjects assigned to the placebo arm of this study.

N/A

17.4* Is study enrollment limited to individuals for whom the commonly used diagnostic/treatment approaches are known to be ineffective or intolerable?

○ Yes ● **No**

17.5* Summarize the risk to subjects in the placebo arm who receive no active treatment for their disease or condition.

Participants enrolled in the regular summer program may not get a chance to learn actively about celebrating differences and increasing cultural awareness to build relationships with people from different backgrounds. In the final year of the study, all schools will receive YES-ERACE.

17.6* How will the condition or disease of subjects in the placebo arm of this study be monitored, compared to the monitoring associated with standard care for this disease/condition?

All participants will complete questionnaires to assess their attitudes and beliefs about diversity, bullying, and racial discrimination, as well as their violent behavior. The control condition is likely to have no effect on these outcomes.

17.7* What criteria will be used to determine that the participation of a subject, who may be receiving a placebo treatment, should be discontinued due to his/her worsening disease or condition?

The control condition is likely to have no effect on the expected outcomes of the intervention.

View: 29. Survey Research
Section: 29. Survey Research

29. Survey Research

Completion of this section is required based on the response provided to question 7-1.5.

29.1* Provide a list of all surveys and interviews used in the study:

Name	# of Questions	Duration	Sensitive?	Disturbing?
00113396 ProgramDevEval_Pretest survey	125	35-45 mins	yes	no
Ame00113396ProgramDevEval_Posttesr	125	35-45 mins	yes	yes
Ame00117777 YES_IDEAS Student Survey Revised 10.28.21 Clean Copy	96	100-120 minutes	no	no
YES-ERACE Wave 1 Survey	125	30-45 minutes	yes	no

29.13* Will the research involve the use of focus groups?

○ Yes ● **No**

29.14* Is any of the material disturbing?

○ Yes ● **No**

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

Survey Detail

29.2* Survey or interview name:

00113396 ProgramDevEval_Pretest survey

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

face to face

29.5* What is the predicted response rate?

90 %

29.6* What is the total number of questions?

125

29.7* What is the anticipated cumulative amount of time required for each subject?

35-45 mins

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

● **Yes** ○ No

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

● **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

Most questions taken from publications.

29.12* Upload the survey instrument here.

Name	Version
AME00113396_ProgramDevEval_Pretest6.24.21.docx(0.01)	0.01

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

Survey Detail

29.2* Survey or interview name:

Ame00113396ProgramDevEval_Posttesr

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

face to face

29.5* What is the predicted response rate?

90 %

29.6* What is the total number of questions?

125

29.7* What is the anticipated cumulative amount of time required for each subject?

35-45 mins

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

● **Yes** ○ No

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

● **Yes** ○ No

29.11* Has the survey instrument been validated or used in standard practice?

● **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

Most questions come from publications.

29.12* Upload the survey instrument here.

Name	Version
AME00113396_ProgramDevEval_Posttest6.27.21.docx(0.01)	0.01

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

Survey Detail

29.2* Survey or interview name:

Ame00117777 YES_IDEAS Student Survey Revised 10.28.21 Clean Copy

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

◯ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

In person or on the internet

29.5* What is the predicted response rate?

90 %

29.6* What is the total number of questions?

96

29.7* What is the anticipated cumulative amount of time required for each subject?

100-120 minutes

29.8* What is the total number of interviews/data collection interactions with an individual subject?

4

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

◯ Yes ● **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

◯ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

◯ Yes ● **No**

29.12* Upload the survey instrument here.

Name	Version
Ame00117777 YES-IDEAS Student Survey Revised 10.28.21 Clean Copy.docx(0.02)	0.02

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

Survey Detail

29.2* Survey or interview name:

YES-ERACE Wave 1 Survey

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

Students will take the pretest survey in person. The three follow up surveys, the participant will chose in person, by phone or internet.

29.5* What is the predicted response rate?

90 %

29.6* What is the total number of questions?

125

29.7* What is the anticipated cumulative amount of time required for each subject?

30-45 minutes

29.8* What is the total number of interviews/data collection interactions with an individual subject?

4

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

● **Yes** ○ No

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

● **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

Most questions were collected from other published studies.

29.12* Upload the survey instrument here.

Name	Version
AME00113396_ProgramDevEval_Posttest6.24.21.docx(0.01)	0.01
AME00113396_ProgramDevEval_Pretest6.24.21.docx(0.01)	0.01
YES-ERACE Measures in Survey(0.01)	0.01
YES-ERACE Survey(0.01)	0.01

View: 32. Data Safety And Monitoring Plan
Section: 32. Data Safety Monitoring Plan

32. Data Safety And Monitoring Plan

Completion of this section is required based on the response provided to question 7-1.10.

The principal investigator (PI) has the ultimate responsibility for the conduct of this research study. The study-specific scientific protocol should include detailed information about tests and procedures employed to safeguard the health and safety of the subjects. Additionally, the PI must prepare a specific data and safety monitoring plan taking into account national guidelines and the study's complexity, risk, and size. The plan should include the administrative processes for recording and evaluating the data quality and integrity. The plan should also specify the responsibilities of research team members and the schedules for reviewing and reporting study progress and adverse events.

Components of this plan relating to the protection of subject privacy and data confidentiality should already have been included in the Confidentiality/Security section of this application.

Additionally, certain members of the research team must complete the PEERRS mandatory training on human subject protection. This includes personnel joining the study team after the initiation of the study.

The Risk Level has been indicated as:

Name	Risk Level	Direct Benefit
HUM00190523	No more than minimal risk	yes

32.1* Indicate who will provide study information and instructions to the subjects beyond what is included in the informed consent document.

Select all that apply:

PI

Co-I

Study Coordinator/Research Assistant

If other, please specify:

32.2* Indicate who will obtain informed consent from the subjects.

Select all that apply:

PI

Co-I

Study Coordinator/Research Assistant

If other, please specify:

32.3* Indicate what mechanism(s) will be used for monitoring subjects and identifying adverse events.

Mechanism (Select at least one:)	Conducted by:
☑ Direct interviews/ physical exams conducted by:	**Select all that apply:** PI Co-I Study Coordinator/Research Assistant If other, please specify
☐ Review of lab work, tests, procedures, etc. by:	**Select all that apply:** There are no items to display If other, please specify
☑ Telephone follow-up conducted by:	**Select all that apply:** PI Co-I Study Coordinator/Research Assistant If other, please specify
☐ Self-reporting by subject	Instructions must be included in the Informed Consent Document.

☐ Other	If other, please specify

Reminder: Adverse Events that come to the attention of any member of the study team must be reported to the PI in a timely manner.

View: 32-1. Data and Safety Monitoring Plan - AE Reporting
Section: 32. Data Safety Monitoring Plan

32-1. Data and Safety Monitoring Plan - AE Reporting

Adverse Event (AE) Reporting

32-1.1* Adverse events will be reported to:

Organization	Reporting Mechanism
☑ **IRB**	**eResearch AE/ORIO submission**
☐ DSMB/DSC/independent monitor	
☐ UMHS Cancer Center DSMB	
☐ Federal oversight agencies (FDA, RAC, etc)	
☐ Sponsor (federal, industry, private, etc)	
☐ Other	

If other, please specify:

32-1.2* Indicate the AE reporting timetable that will be used to report adverse events to the IRB:

Standard IRBMED AE reporting timetable

32-1.3* Affirm that the adverse events will be reported to the IRB according to the following generalized AE GRADING SCALE:

☑

- 0 - No adverse event
- 1 - Mild AE – No treatment needed
- 2 - Moderate AE – Resolved with treatment
- 3 - Severe AE – Inability to carry on normal activities, required professional medical attention
- 4 - Life-threatening or disabling AE
- 5 - Fatal AE

32-1.4* Will Serious Adverse Events (SAEs) be categorized according to the following FDA definition?

Yes

- Death
- A life-threatening adverse drug experience
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly/birth defect
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

32-1.5* Affirm that either the principal investigator or a co-investigator will determine the ATTRIBUTION/RELATEDNESS for each adverse event.

☑

- Definitely related
- Probably related
- Possibly related
- Unlikely to be related
- Definitely not related

32-1.6* Affirm that the EXPECTEDNESS will be assigned for each adverse event according to the following definitions:

☑

- Unexpected adverse events (i.e., has NOT been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, grant application or study agreement, protocol or procedures for this study, investigators' brochure or equivalent (for FDA regulated drugs or devices), DSMB/DSC Reports, published literature, other documentation)
- Expected adverse events (i.e., has been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, grant application or study agreement, protocol or procedures for this study, investigators' brochure or

equivalent (for FDA regulated drugs or devices), DSMB/DSC Reports, published literature, other documentation, or characteristics of the study population)

View: 32-2. Data Safety and Monitoring Plan - Monitoring the Study
Section: 32. Data Safety Monitoring Plan

32-2. Data Safety and Monitoring Plan - Monitoring the Study

Monitoring the Study

32-2.1* Indicate the frequency with which the study team will conduct scheduled assessments of study recruitment, data integrity and quality, adverse events, withdrawals, and compliance with protocol plan.

Every two weeks

If other, please specify:

32-2.2* Study oversight and safety monitoring may be required based on the nature, size, and complexity of the study. Indicate the responsible entities.

Select all that apply:	
☑	**No additional monitoring is required – the nature, size, and complexity of this study does not require additional safety monitoring to that provided by the IRB.**
☐	Independent monitor
☐	Internal committee
☐	Sponsor
☐	Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC)
☐	UMHS Cancer Center DSMB
☐	Other

If other, please specify:

If no additional monitoring is required, jump to 32-2.3.

32-2.2.1 Provide the names and areas of expertise of those providing this additional monitoring

32-2.2.2 Indicate the frequency with which the additional monitoring activities will be conducted.

Annually at the time of the scheduled IRB review

If other, please specify:

32-2.2.3 Indicate the data that will be reviewed.

Select all that apply:
Adverse event review
Subject data
Enrollment
Assessment of minority recruitment
Withdrawals
Protocol violations/deviations

32-2.2.4 If a DSMB or DSC charter exists, upload it here.

Name	Version
There are no items to display	

32-2.3* Monitoring reports will be provided to:

	Organization	Reporting Mechanism
☑	**IRB (required)**	**eResearch**
☐	Federal oversight agencies (FDA, RAC, etc.)	
☐	Sponsor (federal, industry, private, etc.)	
☐	Other	

If other, please specify:

View: 33. Children - Interaction/Intervention Studies
Section: 33. Children

33. Children - Interaction/Intervention Studies

Completion of this section is required based on the response provided to questions in Section 6 and 9-1.1.

33.1* For each research activity conducted with children, indicate the member(s) of the study team that will conduct the activity and briefly describe their expertise with children.

Program Staff are qualified instructors. Program staff are hired based on their extensive experience with children. They will attend extensive training on the YES-ERACE curriculum, human subjects, assents and consents, survey forms as well as identifying and reporting adverse events.

33.2* Describe the adequacy of the research facilities to accommodate children participating in this study.

Each of the research sites are schools, as such they have ample facilities for children's programming. Facilities include classrooms, rest rooms and gyms,

Ame00117777
To meet the Rule of Threes under the UM Minors in Research Policy, we will: 1) for Face to face research we will always have two UM staff present, 2) for UM staff aiding the GISD teachers we will always have two adults in a room where there is only one child present 3) Phone calls for follow-up surveys we will either have two researchers in the same room, or sharing a phone line with a minor, and 4) we only only text from one of two project cell phones. When we text a minor, it will always for from one of the project cell phone. When we text minors will always include the other UM cell phone on all texts..

33.3* Permitted Categories of Research: The federal policy and regulations governing human subject protections specify that research involving children must fall into one of the following permitted categories. Check all categories of permitted research that apply to this study. The information provided here must be consistent with the information in Section 6.

Regulatory Category	Criteria
The research does not involve greater than minimal risk [45 CFR 46.404].	

33.3.1* Provide a justification for how the study complies with the selected requirement.

The 6th, 7th and 8th grade students in this study will attend summer programs four days a week. This is a normal daily activity for many middle school students. The students in this study will also complete surveys on four occasions over a two-year period. Completing surveys is also a normal activity that most 6th-9th grade students do.

Ame00117777

The 6th, 7th and 8th grade students in this study will attend afterschool programs four days a week. This is a normal daily activity for many middle school students. The students in this study will also complete surveys on four occasions over a two-year period. Completing surveys is also a normal activity that most 6th-9th grade students do.

33.4* Does the study require the involvement of children with any physical or mental incapacities?

○ Yes ● **No**

View: 41. Subjects Vulnerable to Coercion
Section: 41. Subjects Vulnerable to Coercion

41. Subjects Vulnerable to Coercion

Completion of this section is required based on the response provided to question 9-1.1 or 9-2.1.

The following subject populations, vulnerable to coercion or undue influence, have been identified for inclusion in the study.
Children

41.1* What is the justification for the inclusion of these subject populations?

This is a research study that compares youth enrolled in a summer program to youth enrolled in Youth Empowerment Solutions for Engaging youth for anti-racism and Cultural Equity (YES-ERACE).

41.2* Describe the additional safeguards that have been included in this study to protect the rights and welfare of these subjects.

We will minimize coercion in a number of ways. We have selected incentives that are not large enough to coerce participants to be in the study if they wish not to be. The consent form and the assent form explicitly state that there are no penalties for not participating in this study. All UM research team members and program staff members will be trained to acknowledge that participation in this study is voluntary and will not coerce any student to participate beyond their will to do so.

View: 44. Additional Supporting Documents
Section: 44 Additional Supporting Documents

44. Additional Supporting Documents

44.1 Please upload any additional supporting documents related to your study that have not already been uploaded. Examples include, but are not limited to, data collection sheets, newsletters, subject brochures, and instructional brochures.

Name	Version
Ame00114207 PROTOCOL YES ERACE_ Program Development and Process Evaluation 7.8.21 Tracked changes.docx(0.01)	0.01
AME0011777 GISD Recruitment Letter tracked changes 12.16.21.docx(0.01)	0.01
AME00117777 YES-IDEAS Child Assent FINAL 12.16.21 Compared documents.docx(0.04)	0.04
AME00117777 YES-IDEAS Parent OPT OUT information Tracked Changes_1.10.22.docx(0.03)	0.03
AME00117777 YES-IDEAS Protocol for IRB_12.8.2021_Track Changes.docx(0.04)	0.04
Ame00117777 YES-IDEAS Student Survey Revised 10.28.21 Compared Documents.docx(0.01)	0.01
Data and Safety Monitoring Plan(0.02)	0.02
Data Management and Security Document(0.01)	0.01
YES Ideas addressed contingencies 12.8.2021.xlsx(0.01)	0.01
YES-ERACE Curriculum Draft for IRB.pdf(0.01)	0.01

View: 45. End Of Application
Section: 45. End of Application

45. End of Application

The form was successfully submitted. Click 'Exit' or 'Finish' to leave the form.

G. SPECIAL REPORTING REQUIREMENTS SPECIAL REPORTING REQUIREMENTS

G.1 SPECIAL NOTICE OF AWARD TERMS AND FUNDING OPPORTUNITIES ANNOUNCEMENT REPORTING REQUIREMENTS

NOTHING TO REPORT

G.2 RESPONSIBLE CONDUCT OF RESEARCH

Not Applicable

G.3 MENTOR'S REPORT OR SPONSOR COMMENTS

Not Applicable

G.4 HUMAN SUBJECTS

Sub-Project ID	Study ID	Study Title	Delayed Onset	Clinical Trial	NCT	NIH-Defined Phase 3	ACT
	288324	Youth Empowerment Solutions- Engaging Youth for Antiracism and Cultural Equity	NO	YES		NO	NO

G.5 HUMAN SUBJECTS EDUCATION REQUIREMENT

Are there personnel on this project who are newly involved in the design or conduct of human subjects research?

No

G.6 HUMAN EMBRYONIC STEM CELLS (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 VERTEBRATE ANIMALS

Does this project involve vertebrate animals?

No

G.8 PROJECT/PERFORMANCE SITES

Organization Name	DUNS	Congressional District	Address
Primary: Regents of the University of Michigan	073133571	MI-012	3003 S. State St Ann Arbor, MI 481091276

G.9 FOREIGN COMPONENT

No foreign component

G.10 ESTIMATED UNOBLIGATED BALANCE

G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

Yes

Estimated unobligated balance: $800,000

G.10.b Provide an explanation for unobligated balance:
Our unobligated balance is due to two factors. First, our Year 1 does not encompass a full year, as we were not notified of funding until six months after the start period. Second, we were not able to implement the program widely in schools due to challenges with COVID-19. While we did conduct a summer pilot of the program, our enrollment numbers were below the target. We are implementing the program in 3 schools in April 2022, and at 6 schools in Fall 2022.

G.10.c If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will be spent

G.11 PROGRAM INCOME

Is program income anticipated during the next budget period? No

G.12 F&A COSTS

Is there a change in performance sites that will affect F&A costs?

No

Section 1 - Basic Information (Study 288324)

OMB Number: 0925-0001

Expiration Date: 02/28/2023

1.1. Study Title *

Youth Empowerment Solutions- Engaging Youth for Antiracism and Cultural Equity

1.2. Is this study exempt from Federal Regulations * ❍ Yes ● No

1.3. Exemption Number ❑ 1 ❑ 2 ❑ 3 ❑ 4 ❑ 5 ❑ 6 ❑ 7 ❑ 8

1.4. Clinical Trial Questionnaire *

1.4.a. Does the study involve human participants?	● Yes	❍ No
1.4.b. Are the participants prospectively assigned to an intervention?	● Yes	❍ No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	● Yes	❍ No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	● Yes	❍ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics (Study 288324)

2.1. Conditions or Focus of Study

- youth violence prevention
- race and cultural equity

2.2. Eligibility Criteria

Youth in 6th, 7th or 8th grades at participating middle schools

2.3. Age Limits	Min Age: 10 Years	Max Age: 15 Years
2.3.a. Inclusion of Individuals Across the Lifespan		
2.4. Inclusion of Women and Minorities	Inclusion_of_Women__Moniorities_and_Children.pdf	
2.5. Recruitment and Retention Plan	Recruitment_and_Retention_Plan.pdf	
2.6. Recruitment Status	Not yet recruiting	
2.7. Study Timeline	Study_Timeline.pdf	
2.8. Enrollment of First Participant (SEE SECTION 6.3)		

Inclusion of Women, Minorities and Children

Women and Minorities. We anticipate enrolling approximately equal numbers of male and female participants in the intervention. Based on the enrollment in the participating summer school sites, we anticipate that the majority of study participants will be African American. Participants will reflect the demographics of Genesee County. See Targeted/Planned Enrollment Tables for more information.

Inclusion Across the Lifespan. Our study will include youth in 6th-8th grade (who range in age from about 10-15 years) in the selected middle schools. We have chosen the middle school students as the period for intervention because children in this age range are in transition from dependence on adults to more independent, peer oriented behavior. In addition, they will be facing the transition in to high school, which can be a stressful process. This is also a critical period for maintaining attachment to school and for forming connections with positive peer and adult role models. Young adolescents are capable of understanding issues that affect their community and are able to plan and carry out community projects with adult support and assistance. Assent will be obtained from all participants using an assent form with developmentally-appropriate wording (see Human Subjects Protection section).

Recruitment and Retention Plan

A. Recruitment. Students from the six middle school sites will be recruited to participate in the study after they have signed up for summer programming, but before programming begins. Schools will be randomized into the YES intervention, or the control group at the time of recruitment. UM researchers will be responsible for the recruitment and obtaining parental permission and student assent.

B. Informed Consent**.** Parent consent and student assent for student participation in the intervention and all assessments will be obtained at the time of recruitment by sending consent forms home along with a postage paid return envelope. We will include a local phone number for families to call to ask any questions they may have about the study. We will also send one follow-up letter and make one call to parents to remind them about returning the consent, and we will make follow-up announcements to students in their classrooms. We will also hold an informational meeting for parents and students prior to the beginning of the intervention to answer questions and assist, as needed, with consents. Parent consent forms will be written at no more than an eighth-grade comprehension level and youth assent forms at no more than a fifth-grade level. In all of the informed consent documents, and also before any interactive research activity, the principle of voluntary participation in research will be explained, reviewed, and emphasized so that participants know that they are free not to disclose information if they so choose, and/or to withdraw from the study at any point. We will also emphasize to parents and students the fact that their decision whether or not to participate in the research will not affect their ability to access any services offered by their school.

C. Survey Completion. The pre- and immediate posttest data will be collected with a paper and pencil questionnaire by UM research assistants. The two other posttests will be collected using methods tailored to their preferred approach which will include: 1) an online questionnaire (Qualtrics) linked via text message, email; 2) mailed questionnaire with return envelope; or 3) telephone on a secure line. If the participant has not returned the survey within 2-3 weeks, UM research assistants will contact the participant via phone to offer to read the survey over the phone. UM research assistants may also contact the participant via email.

D. Retention. Based on GISD's long history with running summer programs, PI Zimmerman's extensive experience running longitudinal studies in Flint, and in the UM-SPH team's experience implementing the YES program in this setting, we anticipate an attrition rate below 15%. We will use a weighted incentive structure to enhance youth participation. All participants will be given financial incentives to complete questionnaires, with incentives increasing for each additional assessments ($5 for Pretest, $10 for immediate post-test, $15 for completing Fall post-test, and $20 for completing Spring post-test). Participants who complete all study waves will also be entered in a drawing for a $50-$100 gift certificate at a local mall (multiple prizes will be available). Participants who fail to complete consecutive assessments will still receive the larger incentives to complete later assessments given the value of these data points to test longitudinal hypotheses, but they would not be eligible for the bonus prizes. These strategies have been successful in obtaining a 96% response rate for a study where we followed Flint youth over a 4 year period (Zimmerman & Schmeelk-Cone, 2003) but we will be collecting data for this study over only a 1 year period per cohort so we expect at least as successful a retention rate. We will also employ multiple contact strategies, including phone calls, text messages, emails, and personal contact at schools. School year post-tests will also be collected via methods of the students' choice so the data collection does not interfere with school and so students can complete the questionnaire at a time and process convenient for them.

E. Oversight. During recruitment phases of our prior studies, our study team has met on a bi-weekly basis to review progress logs, and make decisions around hard-to-reach participations. With hard-to-reach participants we employ a set of procedures to follow-up via phone and vary the times and days we reach out. We will employ this process for the proposed study to ensure adequate tracking of recruitment. To ensure that our enrolled study population has scientific diversity and representativeness, we will compare our recruiting efforts and enrolled sample with our planned enrollment table at our weekly meetings. We will also have periodic meetings with our Advisory Board who can help us stay focused on our goals and problem solve if we are having difficulty with retention. Based on guidelines from the CONSORT Group (Egger et al., 2001), sample information to be assessed at the end of the study includes: 1) number of participants screened for eligibility, 2) number of eligible participants, 3) number of families completing consents, assents, baseline assessments, and randomized to treatment condition, 4) number of participants receiving the YES or Standard summer programs, 5), number of participants lost to follow-up per group, and number of families in the main analysis (Egger et al., 2001). We will conduct analyses to assess group differences in these variables (see Data

Study Timeline

Year 1				
	Q1	Q2	Q3	Q4
Meet with Expert Advisory Board	●	●	●	●
Teaching Tolerance Train the Trainer Training	●			
Curriculum Adaptations (ADAPT-ITT framework)	●	●		
Pilot Test curriculum		●		
Hire and train YES summer school teachers		●	●	
Recruit participants		●	●	
Wave 1 – Pre-test			●	
Implement YES E-ERACE			●	
Wave 1 – Immediate Post (Time 2)				●
Report to DSMB			●	●
Year 2				
	Q1	Q2	Q3	Q4
Wave 1 - Time 3 Follow up	●			
Wave 1 - Time 4 Follow up		●		
Hire and train YES summer school teachers		●	●	
Recruit participants		●	●	
Wave 2 – Pre-test			●	
Implement YES E-ERACE			●	
Wave 2 – Immediate Post (Time 2)				●
Meet with Expert Advisory Board				●
Report to DSMB	●	●	●	●
Year 3				
	Q1	Q2	Q3	Q4
Wave 2 - Time 3 Follow up	●			
Wave 2 - Time 4 Follow up		●		
Hire and train YES summer school teachers		●	●	
Recruit participants		●	●	
Wave 3 – Pre-test			●	
Implement YES E-ERACE			●	
Wave 3 – Immediate Post (Time 2)				●
Meet with Expert Advisory Board				●
Report to DSMB	●	●	●	●
Dissemination of Preliminary Findings				●
Year 4				
	Q1	Q2	Q3	Q4
	●			
Wave 3 - Time 3 Follow up	●			
Wave 3 - Time 4 Follow up		●		
Hire and train YES summer school teachers		●	●	
Recruit participants		●	●	
Wave 4 – Pre-test			●	
Implement YES E-ERACE			●	
Wave 4 – Immediate Post (Time 2)				●
Meet with Expert Advisory Board				●
Report to DSMB	●	●	●	●
Dissemination of Preliminary Findings			●	●
Year 5				
	Q1	Q2	Q3	Q4
Data Analysis and Interpretation Waves 1-4	●	●		

Wave 4 - Time 4 Follow up		●		
Hire and train YES summer school teachers		●	●	
Recruit participants		●	●	
Wave 5 – Pre-test			●	
Implement YES E-ERACE (all 6 schools)			●	
Wave 5– Immediate Post (Time 2)				●
Meet with Expert Advisory Board				●
Report to DSMB	●	●	●	●
Final Data Analysis and Interpretation			●	●
Dissemination of Findings (clinical trials.gov)				●

2.9. Inclusion Enrollment Reports

IER ID#	Enrollment Location Type	Enrollment Location
IER 286312	Domestic	Flint, MI

Inclusion Enrollment Report 286312

1. Inclusion Enrollment Report Title* : Youth Empowerment Solutions- Engaging Youth for Antiracism and Cultural Equity

2. Using an Existing Dataset or Resource* : ❍ Yes ● No

3. Enrollment Location Type* : ● Domestic ❍ Foreign

4. Enrollment Country(ies): USA: UNITED STATES

5. Enrollment Location(s): Flint, MI

6. Comments:

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	1	1	1	1	4
Asian	3	3	0	0	6
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	110	110	4	4	228
White	104	104	2	2	212
More than One Race	30	30	1	1	62
Total	248	248	8	8	512

Cumulative (Actual)

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Section 3 - Protection and Monitoring Plans (Study 288324)

3.1. Protection of Human Subjects	Human_Subjects_Protection.pdf
3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?	● Yes ○ No ○ N/A
If yes, describe the single IRB plan	Single_IRB_plan.pdf
3.3. Data and Safety Monitoring Plan	3.3_Data_Safety_and_Monitoring_Plan_-_revised_9-28-2020.pdf
3.4. Will a Data and Safety Monitoring Board be appointed for this study?	● Yes ○ No
3.5. Overall structure of the study team	Structure_of_Study_Team.pdf

Human Subjects Protection

This research meets the definition of a clinical trial. Before beginning any of the research activities described in this proposal, we will obtain approval from the University of Michigan's Health Sciences Institutional Review Board.

Risks to Participants

Human Subjects Involvement and Characteristics**.** Human subjects will be involved in the proposed research in the following ways: 1) Approximately 410 middle school students, ranging in age from 10-15, will be enrolled in the study. Some of the students will have the opportunity to participate in the YES-ERACE program if their schools is assigned to this arm of the study. The YES-ERACE schools will have other summer program options if parents or their child does not want to participate in the study. Students who do not attend a program school will just receive that school's usual summer program; 2) Participants in both groups will be asked to complete surveys at the time of enrollment, immediately after the intervention, and at six months and nine month follow-ups.

Sources of Materials**.** Research material will include data from written questionnaires completed by participants in the intervention and comparison groups regarding their attitudes, beliefs and behaviors concerning school, leisure time activities, community engagement, and racial attitudes and behaviors. Participants will also be asked to complete a questionnaire assessing their experiences and satisfaction with the intervention. Linking documents (i.e., those containing participant identifying information such as names) will be kept in a password-protected database at a different location (UM-SPH office). No data collection instrument will ever include the child's name. Only code numbers will be used on all forms.

Potential Risks. Participants may feel uncomfortable answering questions about personal behaviors when completing the questionnaires (e.g., about race and cultural equity). They will be instructed that their participation is voluntary and that they can skip any question they do not want to answer. It is also possible that our intervention may not be beneficial, or that participating in this type of intervention could limit their ability to participate in other summer school activities. We will inform participants that they are free to withdraw from the study at any time. We will take precautions described in "Protection Against Risk" below to ensure the protection of all study records.

Adequacy of Protection against Risks

Recruitment. Students from the six middle school sites will be recruited to participate in the study. Schools will be randomized into the YES intervention, or the control group at the time of recruitment. UM researchers will be responsible for the recruitment and obtaining parental permission and student assent.

Informed Consent**.** Parent consent and student assent for student participation in the intervention and all assessments will be obtained at the time of recruitment by sending consent forms home, along with a postage paid return envelope. We will include a local phone number for families to call to ask any questions they may have about the study. We will also send one follow-up letter and make one call to parents to remind them about returning the consent, and we will make follow-up announcements to students in their classrooms. We will also hold an informational meeting for parents and students prior to the beginning of the intervention to answer questions and assist, as needed, with consents. Parent consent forms will be written at no more than an eighth-grade comprehension level and youth assent forms at no more than a fifth-grade level.
In all of the informed consent documents, and also before any interactive research activity, the principle of voluntary participation in research will be explained, reviewed, and emphasized so that participants know that they are free not to disclose information if they so choose, and/or to withdraw from the study at any point. We will also emphasize to parents and students the fact that their decision whether or not to participate in the research will not affect their ability to access any services offered by their school.

Protection Against Risk. Safeguards are in place to assure that rights and welfare of all participants are protected. To minimize the possibility of participant risk, we will monitor participant behavior and/or comments indicating any discomfort or difficulty during intervention sessions and/or with intervention content based on facilitator (and research observer) feedback. Observations will be reviewed during weekly staff meetings and, as needed, if potential adverse events arise (see below). Facilitators and research/recruitment coordinator staff

will be trained and encouraged to use worksheets to document any concerns about participants. With regard to protection against risk in intervention sessions, we will always have two staff members in each session closely monitoring participant behavior. Finally, with regard to confidentiality of the data, all participants will be assigned a subject number and, as noted above, all participant data will be entered into password-protected databases, with identifying information entered in separate files at a separate location. Hard copies of the data will be kept in a locked file cabinet, also separated from any identifying information. Only study staff will have access to the data.

Benefits of Proposed Research to Participants and Others. The proposed study may benefit research participants directly by improving confidence and skills to prevent racism and promote cultural equity related to violence and aggression. Participants' candid responses to questionnaires may provide valuable information regarding the effects of a youth empowerment intervention on youth development and achievement. Thus the potential of risk is outweighed by the potential to benefit both participants and others.

Importance of the Knowledge to be gained. Violence is a common problem among middle school students in the U.S. and is associated with many negative outcomes in the short and long term. YES for Engaging Youth for anti-Racism And Cultural Equity (YES-ERACE) will focus on middle school students because this is a developmental period when independence from parents begin, their own ideas about interpersonal relationships are formative. Empowering children to address violence at this critical developmental period may enable them to resist negative attitudes and behaviors, such as racial prejudice and racism. Further, the middle school years are critical to the developmental trajectories of young adolescents. Research suggests youth empowerment approaches, particularly those that gather and incorporate youth perspectives on the intervention process, and those that involve the participation of supportive adults as we are proposing to do via our adult advocates, are likely to be effective at promoting positive youth development. There is thus much to be gained from the proposed research. Findings will be used to inform other researchers and practitioners to implement and sustain empirically-based model antiracism and cultural equity programs that address violence for middle school youth.

SINGLE IRB PLAN

In accordance with Federal Policy for the Protection of Human Subjects (Common Rule), the study team will submit an application to the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board upon notice of funding. The University of Michigan IRB will provide primary oversight of the study for all study recruitment sites in Genesee County.

Data Safety Monitoring Plan

To address the NIH policy for Data and Safety Monitoring, PI Zimmerman and the research team have developed a system for oversight of the proposed study and its participants. Dr. Zimmerman will be responsible for monitoring the data quality and safety and will report regularly to an independent Data Safety Monitoring Board. (see below: Data Safety Monitoring Board).

PI Zimmerman will be responsible for ensuring that project staff adhere to the UM IRB policies including the following: (1) All participants will understand, agree to, and sign a written consent form before participating; (2) Strict adherence to a participant's right to withdraw or refuse to answer questions will be maintained; (3) Assessments, interviews, and interventions, audio and video recordings will be completely confidential and no names will be associated with the obtained data; (4) Consent forms and identifying information will be kept separate from the actual participant data; (5) All identifying information (consents, tracking data) will be kept locked at all times and computer files will be saved with passwords on secure servers; and (6) Participants will be informed in writing in the consent form on how to contact the PI and IRB office with any questions and/or concerns. Any serious adverse events will be reported as soon as discovery occurs and always within 24 hours of discovery to the UM IRB and to the DSMB. Dr. Zimmerman will also monitor the quality of the data files. Quality control and reliability of screening, baseline and follow-up assessments will be monitored via regular meetings with project managers and through direct observation of research assistants conducting standardized assessments.

The Investigators and project staff will be instructed regarding the importance of and shown how to report any adverse or potentially adverse study events to the PI immediately. The PI is available by cell phone and email and is in regular contact with the study staff. During the study, he and the Co-I's and staff will have weekly conference calls to discuss study progress and troubleshoot; this will be an additional time to check in regarding any concerns with study protocols or participants. If the PI is unavailable, Co-Investigator Eisman will be contacted. We will develop worksheets for facilitators, interviewers, and Coordinators to complete describing the exact nature of and circumstances surrounding the event. These will be reviewed by the PI. All adverse events will in turn be immediately reported to the IRB for review.

Dr. Zimmerman will be responsible for oversight and training for all research staff who are conducting assessments with participants regarding procedures for identifying, managing, and responding appropriately to acute warning signs of distress and will be responsible for providing regular supervision to research staff that have direct contact with participants. Although the study will not directly ask participants about any of issues such as child abuse or suicidality, it is always possible that participants could self-disclose information. We have a number of safeguards in place to ensure that should this occur the appropriate procedures will be followed to protect the youth participants. These include an initial training for all staff that will focus on identifying suspected circumstances of abuse or neglect and provide explicit instructions on: 1) how to handle the situation in the moment and 2) how to report these situations to the appropriate authorities (i.e., the intake department of Flint DHS).

In accordance with UM IRB procedures, life threatening adverse events related to the study will be reported in writing within 24 hours. In addition to the UM IRB, adverse events will also be reported to NIH and to the NIMHD for review and approval. Non-threatening potentially serious adverse events that are causally related to the research (e.g. breach in confidentiality) will be reported in writing within 48 hours. Finally, RAs will be trained in safety procedures to ensure their safety when conducting assessments, and follow-ups. The same crisis reporting procedures for staff safety concerns will apply in terms of immediately contacting Dr. Zimmerman.

Data Safety Monitoring Board

We will form a data safety and monitoring board (DSMB) made up of individuals who are not affiliated with the project and have expertise and experience with data safety and monitoring and human subjects research. PI Zimmerman will perform continuous monitoring of participant safety and will report to the DSMB monthly via email to report progress and annually in person to review emerging trial data. He will report any adverse study events to the DSMB immediately. Confidentiality will be maintained during all phases of the trial including monitoring, preparation of interim results, review, and response to monitoring recommendations. Members of the DSMB will review the research protocol and plans for data and safety monitoring, evaluate the progress of the intervention, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit and make recommendations to the investigators concerning continuation of the trial.

Data Safety Monitoring Board Members:

Elaine Belansky, Ph.D. Director and Research Associate Professor, Center for Rural School Health & Education, Morgridge College of Education, University of Denver. Dr. Belansky is a community-based participatory researcher who has been working in rural, low-income schools for 19 years. She studies how universities and communities can work together to make schools healthy places. Her team developed a strategic planning process called “Assess. Identify. Make it Happen.” (AIM) which helps schools implement school-based environment and policy changes that support physical activity, healthy eating, mental health, and school engagement and decrease bullying, high risk sexual behavior, and drug use. Currently, her team is partnering with rural schools in Colorado to create comprehensive health and wellness plans that ensure students are healthy, safe, engaged, supported and challenged. Belansky has received over $13 million in grants from the CDC, NIH, Private Source, and Private Source

Jose Bauermeister, Ph.D. Penn Presidential Associate Professor of Nursing, School of Nursing, University of Pennsylvania. Dr. Bauermeister’s research focuses on developing and testing comprehensive HIV/STI prevention and care programs for high-risk adolescents and young adults. Currently, he is PI of several intervention projects examining the social and behavioral correlates of HIV risk, as measured by sexual behaviors, alcohol and other drug use, and psychological distress. Dr. Bauermeister has received more than $25 million as principal investigator in research grants, and served as co-investigator on another $115 million in federally-funded research. Dr. Bauermeister’s work has been funded by the National Institutes of Health, the Centers for Disease Control and Prevention, as well as supported by the Private Source Private Source

Emily Ozer, Ph.D. Professor of Community Health and Human Development, UC Berkeley School of Public Health. Dr. Ozer’s research interests include school-based health promotion and prevention programs, post-traumatic stress disorder, violence prevention, and community-based participatory research. She is particularly interested in how the school and classroom contexts in which prevention programs are implemented affect outcomes. Her current research involves a multi-method study of the impact of an empowerment-oriented participatory research intervention on adolescents attending San Francisco public schools.

Overall Structure of the Study Team.

Research Team. PI Zimmerman will lead the study team. He will be responsible for the over-all direction of the research, adaptation and implementation and evaluation of the curriculum. He will assure the effective coordination of all operations and the integration of all partners in the work and provide leadership on the evaluation and analyses of the data. Co-I's Eisman and Stoddard will lead the adaptation and implementation evaluation of the YES E-RACE curriculum. They will be responsible for the overall direction and will assure scientific soundness and effective adaptation and implementation of all aspects of the YES intervention. Co-I's Caldwell, Neblett and Anderson will provide content expertise and guidance in relation to anti-racism and cultural equity and help guide the adaptation and implementation. Co-Is Reischl and Hsieh will lead the data management and outcomes evaluation. All investigators will participate in the development of the measures, analysis and interpretation of the data and dissemination of the findings. Research specialists Grodzinski will manage the project along with Liwosz and Franzen. Ms. Grodzinski will work directly with PI Zimmerman on the day-to-day responsibility of project administration, supervision of staff and research assistants, communication with study partners, meeting facilitation and reporting. She will coordinate the work of research staff, Liwosz, Franzen and Hutchison. Ms. Liwosz will lead trainings, participate in the adaptation and implementation of the curriculum in the schools and assist with data collection and analysis. Ms. Franzen will focus on development of survey instruments and coordination of data collection in the school, participate in the trainings and help manage student research assistants in the implementation phase each summer. Research Specialist Pete Hutchison will lead trainings for the YES teachers, help guide the adaptation process of the curriculum, coordinate with schools and manage the implementation of the summer programs. Web Administrator Joe Alberts will provide support for communications and dissemination for the project including curriculum design and formatting, recruitment material and technical support for the research team. Ms. Ardele Stewart will serve as a research secretary who will handle contracts with schools and process purchases, and incentive payments for the interventions and participants. She will also assist with preparing project materials, scheduling meetings, and preparing meeting notes.

Genesee County Intermediate School District. We will partner with the Genesee County Intermediate School District to implement the YES Curriculum each summer. We will work directly with James Yake, Superintendent, to coordinate the research study in the schools. Schools will hire summer teachers, provide transportation and provide meeting space for the YES program. In addition, schools will provide space for training, and access to office facilities for the staff while they are on site at the school. The schools will also provide access to students for recruitment and data collection.

Advisory Board. We will work with an expert advisory board to advise and assist the research team on curriculum adaptation, implementation and outcome evaluations. In Year 1, we will hold 4 meetings and one meeting each year thereafter. Advisory board members will represent state and local organizations with expertise in the teaching tolerance curriculum, health equity and antiracism training and youth.

We will hold regular (biweekly) research team meetings to manage project tasks at each phase of the study. Meetings will be video and teleconference so all team members may participate. Meetings will provide progress updates and team discussion on adaptation, implementation, data collection and management, as well as interpretation and analysis of the results. Our team meetings will also serve to troubleshoot any challenges if they arise. We will also use these meetings to ensure that we are meeting the all study safety requirements including (1) all participants understand, agree to, and sign a written consent form before participating; (2) strict adherence is maintained to communication regarding the participants' right to withdraw or refuse to answer questions; (3) staff maintain confidentiality both by protecting hard-copy and electronic data collection forms and also by avoiding all unauthorized conversations about individual participants; (4) consent forms and identifying information are kept separately from study related information about patients' socio-demographics, and school records; (5) all identifying information is kept locked at all times and sensitive computer files are maintained on a secured server; (6) coding for ambiguous responses is handled in a way that is consistent and clear across data collectors and over time; and (7) participants are informed in writing how to contact the study PI, the project manager, and the relevant IRB office with any questions or concerns.

Section 4 - Protocol Synopsis (Study 288324)

4.1. Study Design

4.1.a. Detailed Description

Youth violence is a significant public health concern as over 20% report being in a fight, 19% reported bullying someone, and 16% reported weapon carriage.1,2. Violent victimization among youth include mental health sequelae in addition to the physical injury caused by violent behavior.3–5 Racism, the exercise of power against a racial group defined as inferior, is associated with aggression and violence against racial minority youth.6–12 Researchers have identified two pathways by which racism effects youth violence: 1) as a stressor leading to violence; and 2) as a structural factor resulting in more exposure to community-level risk factors.8,13 In addition, racial prejudice may operate to propagate interracial mistrust, fear, hostility, and violence.14,15 Yet, strategies that integrate undoing racism with violence prevention in ways that engage youth in the change efforts have not been systematically studied.

Researchers suggest that positive youth development can be achieved by engaging youth in a wide range of community improvement activities including program development and implementation.16–18 Building on this work and guided by our previous studies of empowerment processes,19–23 we developed an afterschool and summer youth violence prevention program for middle-school students called Youth Empowerment Solutions (YES) for Peaceful Communities.24,25 Our studies of YES describe how the curriculum engages youth in developing a critical understanding of neighborhood violence and in designing and implementing neighborhood improvement projects their neighborhoods and schools that the youth believed would reduce violence.25 We found the YES program reduced violent behavior and increased positive behaviors in a comparison group design26 through the process of empowering youth to think critically about their community, develop plans for change, and implement their plans (i.e., program effects were mediated through empowered outcomes).27,28

We will adapt our YES curriculum to empower youth to address racism and racial discrimination as a way to reduce of violent behavior. YES for Engaging Youth for anti-Racism And Cultural Equity (YES-ERACE) will focus on middle school students because this is a developmental period when racial identity development becomes a central developmental task29 awareness of racism develops,30 their own ideas about interpersonal relationships are formative,31 and when bullying behavior is at its peak.32 Empowering children to address racial discrimination and prejudice may, in part, contribute to reductions in violent behaviors over time. We will work with an Advisory Board of organizations involved in undoing racism work to integrate the Teaching Tolerance (TT)33 curriculum from the Southern Poverty Law Center (SPLC), one of the oldest and well known civil rights organizations in the U.S., into the existing YES curriculum. The YES curriculum has many natural places to integrate TT modules to insure the theme of undoing racism is present in all the activities across the YES-ERACE curriculum. A unique feature of YES-ERACE is that youth will design and implement projects with a focus on undoing racism.

We will test YES-ERACE using a group-randomized trial design in summer programs across 6 middle schools. YES-ERACE projects are youth-driven in partnership with adults. We will examine the effects of the curriculum on individual youths' sense of empowerment, racist behaviors, and violent behavior. We will also evaluate the revisions of the curriculum through testing specific modules and obtaining feedback from youth and school staff. Finally, we will examine both dose and sustainability of YES-ERACE effects. Our Specific Aims are:
1: adapt the YES curriculum to include the Teaching Tolerance curriculum and study the adaptation and implementation process for the new curriculum; 2) test the efficacy of the YES-ERACE curriculum in a randomized design on empowered outcomes which will mediate the effects of YES-ERACE on perpetration of racist attitudes and behavior; 3) test the efficacy of the YES-ERACE curriculum on a model that predicts empowered outcomes will mediate perpetration of racism, and that YES-ERACE effects on aggressive and violent behavior (especially those motivated by racism) will also be mediated by reducing perpetration of racism over time and 4) study the effects of dose-response and sustainability of change on the outcomes from AIMS 2 and 3. We hypothesize that YES-ERACE will increase psychological empowerment (PE) and that these empowered outcomes will reduce racist perpetration which will be associated with less violent behavior (especially race-related violence).

The study will take place during the non-academic summer program (NASP) in 6 middle schools in Genesee County, MI. Genesee County Intermediate School District (GISD) administers and summer programming in Flint and Genesee County. Genesee County's population of 429,000 has remained flat since 1990.91 Flint is the county seat. We selected schools with non-academic summer programs with some racial diversity to increase interracial collaboration. Districts will help enroll children into the study and specially trained GISD staff members will deliver the YES program as a part of their summer programming. The same individuals will NOT provide both the YES program and the usual summer program. Youth in the comparison arm of the study will participate in the usual non-academic summer programming offered by the schools.

Our project will have two phases: Phase 1: Adapting YES-ERACE and documenting the adapation process, where we will will incorporate modules from the Teaching Tolerance (TT) curriculum for 6th-8th graders from the Southern

Poverty Law Center (SPLC), one of the oldest and well known civil rights organizations in the U.S., into the existing YES curriculum; and Phase 2: Documenting implementation and testing the mediation model.

Phase 1: We will revise the existing YES curriculum to include lessons on racism perpetration and teaching tolerance. We will use the ADAPT-ITT (Assessment, Decision, Adaptation, Production, Topical experts, Integration, Training, and Testing) framework to systematically guide YES adaptation, expanding the scope of the intervention to address racial/ethnic discrimination.84 This framework is useful in guiding the process of tailoring an intervention while keeping intact its core effective elements.85 We have assembled an Advisory Board of individuals involved in undoing racism work and TT, positive youth development and violence prevention (see letters of support).

Phase 2: We will randomly assign schools to YES-ERACE or control. All 6-8th grade students attending the summer program will be eligible for the program. Parents will be consented when they sign-up their child for the summer program at their school. Youth will be assented on the first day their summer program. If parents or students opt out of the study, they will be assigned to the usual summer program that the schools offer. Students who do not have parent consent or assent to be in the program and data collection will NOT be allowed to attend YES-ERACE. Once a school is assigned to a condition (already done), they will remain in the condition for all 4 years of the study, and in year 5 all schools will receive the intervention. Youth who attend summer program in multiple years will receive the YES-ERACE program more than once (and up to 3 times). We will analyze the data using dose received and dose delivered as an independent variable to take the repeat exposure into account. For each cohort, the YES-ERACE intervention will be delivered over the course of the summer program. This will also include implementation of the student projects. Students assigned to YES will be broken into groups of 10-12 students. In cases where a teacher may have more than 2 groups, we will provide graduate student assistants (GSA) to help guide the groups through the program activities.24

Data collection. We will collect data at 4 time points. The baseline pretest will be collected before students start the program. We will collect an immediate posttest 1-3 weeks after the youth complete the program. We will collect a second posttest 3-4 months after the immediate post-test, and a third posttest will be collected 8-9 months after the immediate posttest. Based on GISD's long history with running summer programs, PI Zimmerman's extensive experience running longitudinal studies in Flint over several years, and the our team's experience implementing the YES program in this setting, we anticipate an attrition rate below 15%. Yet, we expect much lower attrition because we will only be following youth for less than 1 year and only two post-tests during the school year after the immediate posttest in the summer.

Measures. Our outcome measures are psychological empowerment (PE), racism perpetration, and violent behavior (dependent variable). We will collect demographic data to use as covariates in analyses (i.e., gender, age, race/ethnicity, parent education). PE includes 3 components—intrapersonal, interactional, and behavioral—and that must be tailored to the specific context.20 The intrapersonal component includes multiculturalism, stereotype and prejudice. Multiculturalism will be operationalized with the interethnic ideology measure100 which assesses respondents' value for ethnic diversity, inclusion, and multiculturalism. We will measure prejudice with the Social Dominance Orientation102 scale which assesses endorsement of intergroup hierarchies, norm threat, and power dynamics. We will modify items so they reflect attitudes about interracial hierarchy and dominance. The interactional component focuses on critical thinking about privilege and cultural efficacy. The racism-related subscale from the Privilege and Oppression Inventory103 will be used to measure the participant's awareness of White privilege and race-related stressors. Cultural Efficacy will be measured with the Culturally Self Efficacy Scale for Adolescents104 that assesses how well they relate to and communicate with people from different cultures. The behavioral component focuses on actions people may take that correspond to attitudes and skills from the other two PE components and will be assessed with items that measure prosocial inclusive behaviors105 and bystander behavior106 modified to focus on racist behavior.
Racism perpetration will be measured using items modified from the Perceived Ethnic Discrimination Questionnaire107. We reworded the items to ask how often they have perpetrated different types of racial discrimination behaviors (vs. "experienced discrimination"). We will use the Exclusion/Rejection (7 items), Stigmatization/Devaluation (6 items), and Threat/Aggression (4 items) subscales. The micro-invalidation subscale (9 items) from the Racial Ethnic Microaggression Scale108 will be used to assess frequency of verbal statements made by the respondent that characterizes race and racism as unimportant and irrelevant. Violent Behavior. We will assess bullying with items from the Illinois Bully Scale,109 aggression from the Multisite Violence Prevention Project,110 and violent behavior from the Flint Adolescent study.111 Items from these measures will also be revised to reflect race-related behaviors.

Data analyses will be conducted using Mplus v8112. As a precursor to examining AIM 2, we will test our measurement model of psychological empowerment (PE), racism perpetration, and violence using confirmatory factor analysis to develop measures used in testing specific hypotheses. We will also examine individual indicator variables to examine hypotheses for specific variables. AIM 2: YES intervention effect on Empowerment. To examine the efficacy of the YES-ERACE intervention, we will estimate conditional latent growth models (LGMs) to assess whether receiving the YES-ERACE increased PE over time, while decreasing racism perpetration and violent behaviors. AIM 3: YES-ERACE mediational model. To examine the mediational model from YES-ERACE to violent behaviors, we will first obtain growth factor estimates (e.g., model estimated intercepts, slopes) for each participant. We will then conduct a serial mediation analysis in which YES-ERACE reduces violent behaviors over time by increasing PE and reducing

racism perpetration over time (see Figure 1). Specifically, we will test whether YES-ERACE accelerates improvements in PE, which diminishes racism perpetration over time. Additionally, we will examine whether accelerating decreases in racism perpetration accelerates decreases in violent behaviors. AIM 4: YES-ERACE dose-response effects and sustainability over time. Conditional LGMs will be conducted to approximate the dose effect of YES-ERACE on PE, racism perpetration, and violent behaviors. We will also adjust the LGMs for time, demographic variables, and socioeconomic status. Although LGMs can handle missing data using Full Information Maximum Likelihood (FIML), we will also examine attrition effects using t-tests and chi-square analysis to compare youth without Time 4 data with those who remained in the study. We will examine all study variables (including covariates) within the YES-ERACE and control groups, and between them to examine differential attrition across groups. Our power analysis with 10,000 replications and assuming only 80% of our projected sample of 512 (N = 410) produced ample statistical power (.95) for detecting a small effect of YES-ERACE on the rate of change for each outcome.

4.1.b. Primary Purpose: Prevention

4.1.c. Interventions

Type	Name	Description
Behavioral (e.g., Psychotherapy, Lifestyle Counseling)	Youth Empowerment Solutions - ERACE	YES is an evidence-based active learning program that empowers youth to make positive changes in their communities and to work with adults to support their efforts.119 The goals of the YES program are to provide youth with opportunities for meaningful involvement in preventing youth violence and creating community change, to enhance the ability of adults to support youth in an empowerment framework, and to change the social and physical environment to reduce and prevent youth violence. Youth empowerment activities include workshops for program planning, budgeting, implementation, and evaluation; engaging in community change efforts; developing ethnic identity and pride; and working with adults to achieve these goals. YES uses an empowering strategy to promote positive youth development and reduce risk behavior.We will revise the existing YES curriculum to include lessons focused on racism, appreciation of diversity, and race-based aggressive and violent behavior.

4.1.d. Study Phase: Early Phase 1 (or Phase 0)

Is this an NIH-defined Phase III Clinical Trial? ❍ Yes ● No

4.1.e. Intervention Model: Other

2-Group Comparison Design

4.1.f. Masking ❍ Yes ● No

❑ Participant ❑ Care Provider ❑ Investigator ❑ Outcomes Assessor

4.1.g. Allocation: Randomized

4.2. Outcome Measures

Type	Name	Time Frame	Brief Description

Primary	Psychological Empowerment	Baseline, Immediate post, 3-4 month, 8-9 month	PE includes 3 components—intrapersonal, interactional, and behavioral—and that must be tailored to the specific context. The intrapersonal component for this project includes multiculturalism, stereotype and prejudice. The interactional component focuses on awareness of privilege, interpersonal relations and cultural efficacy. The behavioral component focuses on actions people may take that correspond to the attitudes and skills from the other two PE components and will be assessed with items that measure prosocial inclusive behaviors and bystander behavior modified to focus on racist behavior.
Primary	Racism Perpetration	Baseline, Immediate post, 3-4 month, 8-9 month	We will measure racism perpetration using items modified from the Perceived Ethnic Discrimination Questionnaire (PEDQ; Brondolo et al., 2005) and the Racial Ethnic Microaggression Scale (REMS; Nadal, 2011).
Primary	Violent Behavior	Baseline, Immediate post, 3-4 month, 8-9 month	We will assess bullying and aggressive behavior with 9 items (α =.87) from the Illinois Bully Scale133 and 12 items from the Multisite Violence Prevention Project (2004) to assess aggressive behavior. We will assess more violent behaviors (e.g., hurting people badly enough to warrant medical attention, fighting) using 3 5-point frequency items from the Flint Adolescent study (Hurd et al., 2011; α =.74). These items will also be slightly modified to focus on behaviors related to race/ethnicity in particular.

4.3. Statistical Design and Power — Statistical_Design_and_Power.pdf

4.4. Subject Participation Duration — 12-36 months

4.5. Will the study use an FDA-regulated intervention? — ❍ Yes ● No

4.5.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational Device Exemption (IDE) status

4.6. Is this an applicable clinical trial under FDAAA? (SEE SECTION 6.6)

4.7. Dissemination Plan — Dissemination_Plan.pdf

Statistical Design and Power

Data analyses will be conducted using Mplus v8.[113] As a precursor to examining AIM 2, we will test our measurement model of psychological empowerment (PE), racism perpetration, and violence using confirmatory factor analysis to develop measures used in testing specific hypotheses. We will also examine individual indicator variables to examine hypotheses for specific variables.

AIM 2: YES intervention effect on Empowerment. To examine the efficacy of the YES-ERACE intervention, we will estimate conditional latent growth models (LGMs) to assess whether receiving the YES-ERACE increased PE over time, while decreasing racism perpetration and violent behaviors. As a precursor to examining conditional LGMs, we will fit unconditional LGMs to determine optimally fitting trajectories for each outcome. We will evaluate model fit by examining the chi-square goodness of fit statistics ($\chi 2$)[114], root mean square error of approximation (RMSEA)[115], confirmatory factor index (CFI)[116], and the Tucker Lewis Index (TLI)[117]. We will also conduct robust likelihood ratio tests (LRTs)[118] to select parsimonious LGMs that fits the data well. Next, conditional LGMs will be estimated to investigate whether YES-ERACE, in relation to the control condition, influences the growth terms of PE, racism perpetration, and violent behaviors. Because participants will be recruited from six schools (i.e., 3 for YES-ERACE, 3 for control condition), we will address within-school correlations (ICC) by adjusting the chi-square statistics and standard error as recommended by Muthen and Satorra (1995)[119]. The corresponding equation reflects the model that we will estimate:

$$\textbf{Within-Subject Model: } y_{ti} = \eta_{0i} + \eta_{1i}\lambda_t + \varepsilon_{ti}$$
$$\textbf{Between-Subject Model (Intercept): } \eta_{0i} = \eta_0 + \gamma_1(\text{YES-ERACE})_i + \varsigma_{0i}$$
$$\textbf{Between Subject Model (Slope): } \eta_{1i} = \eta_1 + \gamma_2(\text{YES-ERACE})_i + \varsigma_{1i}$$

In the within-subject model, y_{ti} denotes the outcome for a participant (i^{th}) at a particular time point (t), η_{0i} and η_{1i} are random coefficients that reflect the latent intercept and slope term, λ_t is a proxy for the variable of time, and ε_{ti} denotes error in the within subject-model. In the between-subject models, the intercept and slope (η_{0i} and η_{1i}) serve as dependent variables, γ_1 reflects the effect of YES-ERACE on the overall mean level of the initial outcome, γ_2 reflects the effect of YES-ERACE on the average rate of outcome change over time, and ς_{0i} and ς_{1i} are error terms in the between-subject variations. If YES-ERACE has a significant effect on the slope of an outcome variable, we will test simple slopes between the control and YES-ERACE conditions by:

$$\mu_{yi|x} = \eta_0 + \eta_1\lambda_t + \gamma_1(\text{YES-ERACE}) + \gamma_2\lambda_t(\text{YES-ERACE})$$

We will probe the interaction between time (λ_t) and YES-ERACE by estimating simple intercepts and slopes for participants in the YES-ERACE and control conditions as shown in this reduced-form equation.[120]

AIM 3: YES-ERACE mediational model. To examine the mediational model from YES-ERACE to violent behaviors, we will first obtain growth factor estimates (e.g., model estimated intercepts, slopes) for each participant. We will then conduct a serial mediation analysis in which YES-ERACE reduces violent behaviors over time by increasing PE and reducing racism perpetration over time (see Figure 1). Specifically, we will test whether YES-ERACE accelerates improvements in PE, which diminishes racism perpetration over time. Additionally, we will examine whether accelerating decreases in racism perpetration accelerates decreases in violent behaviors as indicated in Figure 1. Like AIM 2, we will account for the non-independence in the individual-level data by controlling for within-school correlations. To evaluate the proposed longitudinal mediation from YES-ERACE to violent behaviors, we will conduct tests of joint significance (TJS).[121] This test can determine whether the product of coefficients from individual paths (e.g., YES-ERACE → slope of PE) within the indirect effect is statistically significant.[122] The TJS method more power and yields lower Type 1 error rates than the bias-correct bootstrap method for estimating indirect effects.[122] Chi-square goodness of fit statistics, RMSEA, CFI, and TLI will be examined to examine model fit.

AIM 4: YES-ERACE dose-response effects and sustainability over time. Conditional LGMs will be conducted to approximate the dose effect of YES-ERACE on PE, racism perpetration, and violent behaviors. We will also adjust the LGMs for time, demographic variables, and socioeconomic status. The participants' cumulative exposure to YES-ERACE units will range from 0 (i.e., control condition) to 24 (i.e., participant received all 6 YES-ERACE units in 6^{th}, 7^{th}, & 8^{th} grades). We will build upon the unconditional LGMs from AIM 2 by including sociodemographic variables as time-invariant predictors and dosage as a time varying predictor:

$$y_{ti} = \eta_0 + \sum\gamma_{0k}(\text{covariates})_{ki} + \eta_1\lambda_t + \lambda_t\sum\gamma_{1k}(\text{covariates})_{ki} + \sum\beta_t(\text{dosage})_{ti} + (\varsigma_{0i} + \lambda_t\varsigma_{1i} + \varepsilon_{ti})$$

The corresponding equation reflects the combined within and between subject models, in which yti is the observed outcome measured at time t for participant i; η0 and η1 two latent growth factors (intercept, slope); λt are time scores; γ denotes the effects of the covariates (e.g., sex) on the latent factors; βt denotes the effect of dosage on the corresponding yti; and (ς0i + λtς1i + εti) representing random components of the within- and between-subject growth trajectories. We will use the same model indices noted above to test hypotheses.

Attrition Analyses. Although LGMs can handle missing data using Full Information Maximum Likelihood (FIML), we will also examine attrition effects using t-tests and chi-square analysis to compare youth without Time 4 data with those who remained in the study. We will examine all study variables (including covariates) within the YES-ERACE and control groups, and between them to examine differential attrition across groups.

Power Analyses. AIM 2: We conducted a Monte Carlo (MC) simulation to evaluate the statistical power of a model in which YES-ERACE accelerates increases in PE, while decreasing racism perpetration and violent behaviors. For the outcome, we specified an intercept (baseline) and slope (rate of change) term for the LGM. We adjusted standard errors for non-independence and specified conservative effect sizes between YES-ERACE and controls for the intercept (.10) and slope (.15) for each outcome. We also specified conservative mean intercept (.10) and slope (.05) estimates. The simulation with 10,000 replications and assuming only 80% of our projected sample of 512 (N = 410) produced ample statistical power (.95) for detecting a small effect of YES-ERACE on the rate of change for each outcome.

AIM 3: Our MC simulation to approximate the power of a serial mediational model in which YES-ERACE diminishes the slope (rate of change) of violent behavior by positively shaping the slope of PE and negatively shaping the slope of racism perpetration (see Figure 1). We specified conservative estimates for the slope (.03) and for associations between the slope factors (i.e., .15 to .20). After adjusting for the non-independence in the data, the simulation produced a power of .89 to detect an indirect effect from YES ERACE to the slope of violent behaviors (through PE and racism) with a sample size of 410 (80% of projected sample).

AIM 4: Our MC simulation to conduct power analysis for detecting dose effects indicated statistical power in the 83-.96 range for detecting dose effects on the outcomes at each time point. The LGM with time invariant (i.e., covariates) and varying (i.e., dose) predictors estimated the power for detecting a conservative slope term (i.e., -.05) with the 80% sample size (N=410). We also included conservative estimates for the time-varying effects of dose on the outcome variable at each measurement period (i.e., .05-.15). We specified 10,000 replications and adjusted for the non-independence in the data using a sandwich estimator.

Dissemination Plan

We will share information about this/these trial(s) via timely registration, updates, and results reporting in ClinicalTrials.gov in accordance with NIH policy. The informed consent documents used for this/these trial(s) will include statements to inform participants that information about the trial will be posted in ClinicalTrials.gov . The University of Michigan's Human Research Protections Program (HRPP) Operations Manual is the primary location where rules, policies, practices, and guidance pertaining to the University's HRPP are provided, including Part 11 (section II.H) which addresses the requirements to register trials and report results. Compliance with these provisions is monitored by designated components of the UM HRPP.

We will also disseminate our findings through academic journals, presentations and conferences. In Year 3, 4, and 5 we will share preliminary findings and implementation study results. In Year 5 we will disseminate our final outcomes and study results.

In addition to study findings we will disseminate the YES E-RACE curriculum for practitioners and professionals. We will begin with a focus on our local school partners and will include three steps. First, we will provide the program to comparison schools in year 5 and have included budgeting for this purpose. Second, we will provide our complete YES-ERACE curriculum and training materials to the school districts following completion of the study. Third, we will provide training to any schools in the GISD who would like to include the YES-ERACE program in their summer programming. In addition we will post the curriculum online on the University of Michigan Tech Transfer website, along with other YES curricula and material. We will also share it on the YES website (yes.sph.umich.edu) and social media.

Section 6 - Clinical Trial Milestone Plan (Study 288324)

6.1. Study Primary Completion Date	10/01/2021	Anticipated
6.2. Study Final Completion Date	02/28/2025	Anticipated
6.3. Enrollment and randomization		
Enrollment of the First Participant (Study Start Date)	04/01/2022	Anticipated
25% of planned enrollment recruited by	09/01/2022	Anticipated
50% of planned enrollment recruited by	09/01/2023	Anticipated
75% of planned enrollment recruited by	09/01/2024	Anticipated
100% of planned enrollment recruited by	09/01/2025	Anticipated
6.4. Completion of primary endpoint data analyses	09/01/2025	Anticipated
6.5. Reporting of results in ClinicalTrials.gov	09/30/2025	Anticipated
6.6. Is this an applicable clinical trial under FDAAA?	❍ Yes ● No	