

Train Your Brain: A Pilot Project to Improve Memory and Decision Making
NCT05879198
Final Approved Protocol
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STUDY TITLE: Train Your Brain: Improving Memory and Decision Making to Improve Outcomes among Youth

1. STUDY AIM, BACKGROUND, AND DESIGN ABSTRACT

Youth exposed to early childhood adversity are at increased risk for engaging in problematic substance use, leading to myriad negative health outcomes, including HIV exposure, injury, and impaired driving. Adolescents from low resource communities' evidence elevated rates of exposure to adverse childhood experiences yet have limited access to evidence-based preventative interventions. Thus, there is a critical need for services that can feasibly target specific mechanisms linking early adversity to the onset and escalation of substance use in traditionally underserved communities.

One such target is delay discounting (DD), the tendency to select small, immediately available rewards at the expense of larger, delayed rewards. DD has been linked to early substance use initiation and more frequent and severe use across adolescence. Moreover, youth exposed to early childhood adversity evidence more problematic levels of DD, indicating that DD may be a pathway by which early trauma exposure leads to drug and alcohol use.

Research from our team suggests that computer-based interventions targeting proximal cognitive skills, specifically executive functions, can improve rates of DD. Moreover, computerized interventions are highly transportable and scalable, making them ideal for dissemination in low-resource communities. The current project proposes to pilot a computer based working memory training program to improve DD and prevent substance use among at risk adolescents in traditionally underserved areas (Detroit and Flint, MI).

Our first goal or phase of the project (Aim 1) is to conduct a small case series with up to 50 youth participants and 50 parent/guardian participants ($n=100$) to evaluate the preliminary feasibility of delivering a computer-based intervention in a community setting serving low income adolescents. This case series will be used to determine if the intervention can be delivered feasibly, acceptability, and at sufficient dosage. This includes conducting a subgroup cohort ($n = 60$) of 1-3 focus group sessions to garner feedback and evaluate the active training intervention sessions for continuous quality improvement as well as provide feedback on assessment measures, with a specific focus on measures of delay discounting and environmental components that impact decision making and perceived stability. We will also administer key informant interviews to evaluate the utility of our recruitment and retention procedures as well as identify barriers to participation.

Results from the study will inform future efforts substance use prevention efforts targeted at youth exposed to adverse childhood experiences. These findings will also refine future models of intervention delivery in traditionally underserved communities.

2. SUBJECT POPULATION AND ELIGIBILITY

Please note that youth will be recruited to participate in either the intervention group or the focus group. No youth will be purposefully recruited from the intervention group to take part in the focus group; however, youth who have taken part in the intervention group and opt to take part in the focus group will be allowed to do so.

Youth Intervention Group

Subject Population: Youth

Youth and their guardians will be invited to participate in the study if they meet the following inclusion criteria:

- (1) Youth must be between the ages of 12 and 14 and have a parent/guardian willing to provide consent for their participation.
- (2) Youth must be proficient in English in order to validly complete all assessment measures and take part in the computer-based training.
- (3) Youth must be willing to commit to participate in two to three 20–30-minute computer-based trainings for five to seven weeks.
- (4) Youth must be willing to take part in assessments before and immediately following the intervention as well as a confidential interview with researchers after completing the computer sessions
- (5) Youth and their guardians must have access to a cell phone, email, and/or internet services

Youth will be excluded based on the following exclusion criteria:

- (1) currently psychotic;
- (2) currently suicidal or evidence active suicidal ideation;
- (3) currently diagnosed with a substance use disorder.

Subject Population: Parents/Guardians Inclusion Criteria

- (1) Willing to provide consent for their participation
- (2) Proficient in English in order to validly complete all assessment measures
- (3) Youth must be willing to commit to participate in two to three 20-30 minute computer based trainings for five to seven weeks.
- (4) Access to a cell phone, email, and/or internet services

Parents/Guardians will be excluded based on the following exclusion criteria:

- (1) currently psychotic;
- (2) currently suicidal or evidence active suicidal ideation;
- (3) currently diagnosed with a substance use disorder.

Enrollment and/or Screening – Active Intervention

All participants will be recruited from the YMCA of Metropolitan Detroit, Flint Freedom Schools Collaborative (FFSC), and the Downtown Boxing Gym (DBG), which offers academic, athletic, and creative programming for youth in the Detroit and Flint areas. Researchers will work with YMCA/FFSC/DBG staff to identify appropriate locations within the facilities to post fliers about the project. Participating sites, staff and community liaisons will also speak to groups of adolescents participating in regularly scheduled programming attended by eligible participants at the facilities to determine interest. For example, summer programming activities provided by the participating sites. Parents of interested adolescents will be contacted by study staff to screen and determine study eligibility. Screening can take place in person or via phone. All interested adolescents will be screened by research staff for inclusion in the study.

Screening will be done to ensure eligibility. Following the initial screener to assess for inclusion/exclusion criteria, eligible adolescents and their parents/guardians will complete the consent/ assent process. Once consent/assent has been obtained a baseline assessment

packet, evaluating current levels of WM and related executive functions, delay discounting, substance use and exposure to adverse experiences.

Youth Focus Group

Assessment Focus Group Subject Population: Youth/Young Adults

Youth and their guardians will be invited to participate in the focus group if they meet the following inclusion criteria:

- (1) Youth/young adults must be between the ages of 12 and 17 and have a parent/guardian willing to provide consent for their participation OR between ages 18 and 21 and able to provide consent for oneself
- (2) Youth/young adults must be proficient in English
- (3) Youth/young adults must be willing to attend 1 focus group session
- (4) Youth/young adults and their guardians must have access to a cell phone, email, and/or internet services
- (5) Michigan resident

Youth/young adult will be excluded based on the following exclusion criteria:

- (6) Self-disclosure of psychosis
- (7) Self-disclosure of current suicidal or evidence active suicidal ideation
- (8) Self-disclosure of a substance use disorder

Intervention Focus Group Subject Population: Parents/Guardians of youth participants ages 12 to 17

- (1) Willing to provide consent for their child's participation
- (1) Proficient in English
- (2) Child must be willing to commit to participate in 1 focus group session
- (3) Access to a cell phone, email, and/or internet services

Parents will be excluded based on the following exclusion criteria:

- (1) Self-disclosure of psychosis
- (2) Self-disclosure of current suicidal or evidence active suicidal ideation
- (3) Self-disclosure of a substance use disorder

3. STUDY PROCEDURES

Procedures for Intervention Group:

Eligible youth (up to n=50 and their parents/guardians, up to n=50) will be recruited for participation in the intervention portion of the study. Fliers will be posted and distributed at each facility and announce information during regular facility programming. Interested youth and their parents/guardians will be given a study phone number, email and/or QR code to contact if interested. Research staff (including research assistants IRB approved community liaisons under the supervision of the PI (Felton) will conduct screening instruments over the phone or in-person (in a private, on-site room) and baseline assessments will be scheduled for eligible participants. We conservatively estimate enrolling participants at a rate of 4-5 youth

per month. Following screening, research staff will review the consent information with eligible and interested participants. They will review the key information in the informed consent document with the participant and allow enough time for any questions to be answered. During the consent process, all individuals will be informed that participation is completely voluntary, will be kept confidential, and will not impact their access to services in any way. After reviewing the consent information with the participant and answering any questions, research staff will do one of the following: 1) For participants that are screened over the phone, research staff will send a link to the consent form via text or email, using DocuSign and/or REDCap's e-consent framework, for the participant to review and electronically sign prior to starting any study procedures. A PDF of the completed consent form will be available to the participant for download after they provide their consent. 2) For participants that are screened in person, research staff will pull up the e-consent form in REDCap for the participant to complete on a study computer or paper consent. If consent is collected on paper, participants will be provided with a copy of the signed consent.

Following informed consent and assent procedures, eligible participants and their parents will be scheduled to complete a baseline assessment protocol, including measures of youths' exposure to early life adversity, working memory (WM), delay discounting (DD), and substance use (SU) risk indicators. Baseline and post intervention assessments (surveys and key informant interviews) will be collected electronically (e.g., REDCap, Millisecond, Pearson, etc.) by mail, phone, or in-person. Individuals who complete their surveys via texting have consented to receive text messages: The following text messages will be sent:

Parent: Hi Parent! Please complete your surveys for the Train Your Brain project by selecting this link: <Twilio via REDCap link>

Adolescent: Hi there! Please complete your surveys for the Train Your Brain project by selecting this link: <Twilio via REDCap link>

All participants in the first phase of the project will receive the active condition. Each participant will be assigned a unique login for the self-guided training sessions and participation (including attendance and performance) will be electronically monitored. Research staff including IRB approved community liaisons (individuals who take part in programming at the YMCA, FFSC, or DBG and hired to work as part of this project) will be stationed at each data collection site during the activity period to help set up training sessions and remind participants to complete the intervention activities when applicable.

Aim 1 (Intervention Development): To engage stakeholders (adolescents, parents, staff and leadership from youth-serving organizations) in the development of a WM training program for reducing DD by conducting a small open-label series . Results will inform an adaptation of the intervention with respect to: (1) feasibility (measured using enrollment, attendance, and retention data); (2) acceptability and appropriateness of the intervention (measured using surveys, and key informant interviews); and (3) necessary intervention dosage to produce change in DD. All participants in the phase of the project will receive the active training and compensation (detailed below).

Active Training. Active training will consist of approximately 15 computer sessions during which participants will complete eight WM training programs. This initial number of sessions is based on previous research but will be a specific focus. Programs are consistent with those used in previous trials. Active training sessions include: Sequenced Recall of Digits – Auditory, Sequenced Reverse Recall of Digits – Auditory, Sequenced Recall of Digits – Visual, Sequenced Reverse Recall of Digits – Visual, Sequenced Recall of Words – Auditory, Sequenced Recall of Words – Visual, Sequenced Reverse Recall of Words – Auditory, Sequenced Reverse Recall of Words – Visual. Additional validated visual and working memory capacity measures may be added as determined by the clinical expertise of the PI. For example, this includes but is not limited to the Corsi Block Tapping Task. Each session will take approximately 20-30 minutes to complete. In line with preliminary studies, youth will also receive a small incentive ((a “ticket” that can be turned in for prizes at the end of the program) for each computer training program they complete, as well as tickets for each module of the training that they improve on from their previous scores. We will also gather specific feedback regarding this approach.

Study Assessments and Duration: Adolescents: Adolescent participants will be asked to complete 10-15 computer sessions at a rate of 2-3 computer sessions per week. Each computer session will take about 20 to 30 minutes to complete. Adolescents will also be asked to participate in two assessment sessions which will take about 45-60 minutes to complete. One before the computer sessions and one immediately after they complete their computer sessions (between 5-7 weeks). Finally, they will be asked to participate in a brief 30-minute interview 2 weeks after completing the computer sessions about their experience in the study. With parent and child permission, the interview will be audio recorded. In total, adolescents will participate in 13-18 study session visits over the course of 9 weeks.

Parents: Will be asked to participate in a baseline assessment (before their child’s computer sessions begin), a post intervention assessment when child’s computer sessions are complete (5-7 weeks post baseline) and a key informant interview approximately two weeks after completing sessions (9 weeks). The interview will be audio recorded, with their permission.

Interview: A qualitative interview will be conducted with key stakeholders a couple of weeks after completing the intervention to better understand the intervention and how participants found it. The interviews will be recorded and transcribed for analysis.

Procedures for Focus Group Subgroup Cohort Study:

Focus Group Subject Population: Youth/Young Adults

Youth and their guardians or young adults will be invited to participate in the focus group if they meet the following inclusion criteria:

- (1) Youth must be between the ages of 12 and 17 and have a parent/guardian willing to provide consent for their participation OR between ages 18 and 21 and able to provide consent for oneself
- (2) Youth must be proficient in English
- (3) Youth must be willing to attend at least 1 to 3 focus group sessions
- (4) Youth and their guardians must have access to a cell phone, email, and/or internet services

(5) Michigan resident

Youth/young adults will be excluded based on the following exclusion criteria:

(1) Self-disclosure of psychosis

(2) Self-disclosure of current suicidal or evidence active suicidal ideation

(3) Self-disclosure of a substance use disorder

Focus Group Enrollment and/or Screening.

Participants will be recruited from the Michigan community. The study PI has access to the focus group target population via their extensive community engagement and outreach work throughout the region. Parents of interested adolescents will be contacted directly via email, phone, or in-person by study staff to determine study interest and eligibility. Additionally, study staff will hand out recruitment flyer(s) to community stakeholders and agencies that work with children as well as word of mouth approaches to recruit participants. If interested, screening will take place in person or via phone. All interested adolescents will be screened by research staff for inclusion in the study.

Focus Group Recruitment

Focus group participants will be recruited separately from the intervention condition; however, youth that participated in the intervention condition will also be allowed to participate. Parents or guardians of eligible youth will provide consent for their child's participation. Contact will be made via phone, email, or text to parents/guardians. Interested youth and their parents/guardians or young adults will be given a study phone number and email to contact if interested. Research staff will conduct screening instruments over the phone or in-person (in a private, on-site room) to ensure eligibility. Following the initial screener to assess for inclusion/exclusion criteria, eligible youth and their parents/guardians (or youth between 18 and 21 years old who are able to consent for themselves) will complete the consent/ assent process.

Focus Group Consent

Following screening, research staff will review the verbal consent information with eligible and interested parents and guardians of participating youth and/or youth ages 18 to 21 years old who are able to provide consent for themselves. These processes will include enough time for any questions to be answered. During the consent and assent process, all individuals will be informed that participation is completely voluntary, will be kept confidential, and will not impact their access to services in any way. After reviewing the consent and assent information with the parent and adolescent, research staff will document verbal consent collection and assent in REDCap. Up to 60 youth (ages 12 to 21) will be enrolled.

Focus Group Procedures

Following informed consent and assent procedures, eligible participants will be scheduled to participate in a focus group session. Each focus group will last approximately 60-90 minutes. Each session will take place virtually or in-person at a public location such as the library or at a community partner site. Up to three focus group sessions per participant will be scheduled as needed. We expect the focus group sessions will take place over the course of approximately 1-2 months depending on participant and study staff availability.

All participants will be asked to review the study procedures for their insights, feedback,

and suggestions for improvement. This includes but is not limited to their review of the assessment battery and computer-based active training program. Each focus group session will be recorded and transcribed for analysis. Participants will be compensated \$25 with a study provided ClinCard for each focus group session they attend (up to 3).

Focus Group Compensation

Adolescents and young adults will be compensated \$25 for each focus group session they attend, up to 3 sessions in total and \$75 in total compensation.

Summary of Enrollment Numbers.

The following chart summarizes the total possible enrollment by component (intervention vs. focus group) for youth participants under 18, youth participants over 18, and parents/guardians of youth participants under 18. Please note, all numbers are enrollees “up to” the number indicated in the box.

	Clinical Trial	Focus Group (revised)
Total possible <i>N</i> of youth participants <18 years old	50	60 total youth (ages 12-21)
Total possible <i>N</i> of youth participants >=18 years old	0	
Total possible <i>N</i> of parents of youth participants participating in the clinical trial	50	0
TOTAL POSSIBLE ENROLLEES PER COMPONENT (Clinical Trial vs. Focus Group)	100	60

Data Management and Quality Control. We have developed a number of procedures to monitor the collection of data in our communities. Most important among these is the need to extensively train and supervise research staff in accurately administering all assessments and entering data. For self-report questionnaires, we will use computer-assisted data collection approaches (i.e., REDCap, Millisecond, etc.) that will allow participants to directly input their own data. Study procedures that take place over video conferencing streams will utilize secure, encrypted video conferencing channels to conduct study related tasks. Audio recordings will be stored on a secure folder on the HFHS drive. Files will be transcribed and identifiable information will be redacted. Behavioral measures of delay discounting will also be completed entirely on the computer.

All other assessments will be double-entered and cleaned by research staff. Data files will be backed up weekly and stored on a password-protected computer. Staff will attempt to collect all missing assessments immediately post collection but no later than 1 month after study completion. Missed or incomplete assessments are anticipated. As a result, study staff will document the reason why assessments are missed in the study files. Missed assessments will not be documented or reported as protocol deviations for the purposes of this study.

Power Analysis and Sample Size Considerations. The primary purpose of this grant is to establish implementation factors and detect signal in constructs of interest (i.e., DD and WM) in preparation for a subsequent, fully-powered trial. Therefore, we present information

regarding required sample size for completeness, but highlight that this project is not intended to be powered to examine clinical effectiveness.

Missing Data. Because missing data can lead to biased estimates of effects and, consequently, incorrect interpretations of clinical trial outcomes, we will attempt to handle missingness in a number of ways, including employing participant retention procedures and collecting assessments even if the participant did not complete any or all of the computer training sessions. If data is missing, we will examine patterns of missingness to determine if specific missing data algorithms, such as multiple imputation or full information maximum likelihood approaches, would be appropriate for use with our data.

Next Steps. Findings for the current study will provide critical information for successfully completing future aims of this grant, including an RCT examining effectiveness of WM training in reducing adolescent DD and risk for SU, guided by the results of the current study. Results may also support utilizing the intervention adjunctively alongside more content-focused prevention efforts, supporting future comprehensive prevention trials to decrease SU. Developing cognitive training interventions targeting mechanisms of SU liability specific to adolescents exposed to early adversity has the potential to enhance both basic understanding of determinants of SU and intervention approaches in a vulnerable, traditionally underserved adolescent population.

4. ANTICIPATED RISKS

A number of precautions will be taken to mitigate each of the risks outlined above. With regard to confidentiality, we will take steps to ensure participant data remains secure. All research staff, including community liaisons, will be trained in the protection of human subjects and will be instructed in maintaining confidentiality. In order to de-identify data, we will assign each participant a random number. Only these numbers will be associated with the assessment materials and training performance. One master document that links participant names to these numbers will be retained by the PI in a locked file cabinet, behind locked office doors in the HFHS laboratory space. In the community setting, YMCA/FFSC/DBG staff will not be informed who has been screened and enrolled and participants will be assured that the decision to take part in the study will not affect their status at the YMCA/FFSC/DBG nor their access to YMCA/DBG programming. Community liaisons will not have access to any assessment materials, nor will they be able to track computer-based training progress. While participation in the program involves completing training in computer rooms at community based recruitment sites (thus making it possible for other youth to observe participants being administered the intervention), we will attempt to conceal participation status in a number of ways. Community liaisons and research staff will be trained to take reasonable precautions to prevent revealing adolescent participation in the program, including closing the door to the computer room and not referring to participants' status in the program outside of the computer room. Participants will also be given the opportunity to complete assessment measures either over a web-based survey collection tool (REDCap) or in a secure and private location at the YMCA/FFSC/DBG. All parents/guardians will be provided with a list of free and low-cost mental and behavioral health resources in the Detroit and Flint areas. Upon request, parents/guardians will also be provided deidentified, aggregated data on adolescent substance

use to help understand normative trends around substance use.

We expect any discomfort adult or adolescent participants may feel while completing assessment questionnaires (i.e. frustration, boredom, and fatigue) to be short-lived. However, in the event that participants are either disturbed or concerned about reactions to the questionnaires, we will encourage them to discuss these concerns with the research staff. They will be put in touch with the PI (Felton) if concerns are not satisfactorily addressed. Because alcohol and drug use is illegal for all adolescent participants, there is a risk of legal repercussions related to the disclosure of confidential data. We will discuss with all participants and their guardians the nature of the Certificate of Confidentiality during the assent and consent procedures. If participants still report feeling uncomfortable answering certain questions, they will be reminded that they are allowed to skip items and still be compensated for participation. Based on previous experiences collecting substance use data from adolescents (i.e. R01 DA018647), we anticipate very low levels of non-response.

Once enrolled in the study, any evidence of participant's suicidal ideation, current/ongoing trauma exposure, and/or urgent physical and mental health concerns will be assessed by the research team throughout treatment and follow-up assessment sessions. Although it is unlikely that a participant will spontaneously disclose suicidality or homicidality, any incidents in which this happens will be immediately addressed in a number of ways. Research staff will contact the participants' parents/legal guardians and provide a free crisis line number. Research staff will also contact the PI (a clinical psychologist) immediately who will attempt follow-up directly with the participant and their parents within 24 hours to gain additional context and support in connecting the family with requested mental health resources.

Research staff will bring any adolescents who report engaging in dangerous levels of risky behaviors, as indexed by severe and frequent episodes of substance use, to the attention of the investigator team during regular meetings. Based on information from study evaluations, Drs. Felton (PI) and Johnson (Co-I located in Flint, proximal to the Flint Freedom Schools, and both licensed clinical psychologists) will determine the appropriate course of action. These actions will follow protocols and regulations stipulated by the community site (either YMCA/FFSC/ or DBG), HFHS IRB, NIH and the State of Michigan. In extreme circumstances, this may involve contacting authorities. Participants will be allowed to remain in the study, but their data will not be used and a replacement participant will be recruited. Incidents of suicidality or abuse not deemed to involve imminent danger will be considered an adverse event (AE) and incidents where imminent danger is evident will be considered a serious adverse event (SAE). Both AEs and SAEs will be promptly reported to appropriate institutional contacts.

5. ANTICIPATED BENEFITS

For youth participating the current study, the potential benefit of taking part in the clinical trial is the possible improvement in working memory, related executive function skills, and delay discounting, as well as subsequent improvement in health-related behaviors.

More broadly, for all youth participants, knowledge gained from this study will inform future substance use prevention efforts and will also help in refining dissemination procedures in low-resource communities. Thus, the primary benefit of the proposed research to the community is to inform future interventions that may reduce rates of adolescent substance use

and improve public health in this traditionally underserved area.

6. RENUMERATION/COMPENSATION

Youth Intervention Group: Compensation will be skewed such that rates of compensation will increase across the course of the intervention.

Child:

1. Baseline assessment = \$10
2. Post-intervention assessment = \$15
3. Key informant interview = \$20
4. Training session = 1 ticket (that can be turned in at regular intervals for prizes)
5. Improvement = 1 ticket/improved training module
6. Certificate of completion

Parent:

1. Baseline assessment = \$25
2. Post-intervention assessment = \$25
3. Key informant interview = \$25

Tickets issued for improved training modules are based upon the completion of computer training modules (AKA challenge tasks). Tickets can be turned in for prizes under \$10 in value. Examples of prizes include gift cards, games, school supplies, sporting posters and goods, one size clothing such as socks, fidget toys, stickers, candy, slime, and body care products like lotion. These incentive amounts were determined in collaboration with potential members of the Community Advisory Board and deemed commensurate with other interventions currently being conducted in Detroit and Flint and not coercive to potential participants.

Youth Focus Group: Compensation will be \$25/focus group provided by ClinCard following each focus group.

7. COSTS

Participation in the study is at no cost to the participants.

8. ALTERNATIVES

There are no other alternatives to participation.

9. CONSENT PROCESS AND DOCUMENTATION

Informed consent and assent will be obtained at the initial screening assessment. As part of this process, participants, and guardians will be given a detailed description of the purpose and procedures of the study, emphasizing our policy regarding privacy and confidentiality. Only individuals giving informed and voluntary consent/assent will be enrolled. All consent and assent documents will be reviewed and approved by the HFHS IRB prior to administration.

10. WITHDRAWAL OF SUBJECTS

Subjects may voluntarily withdraw from the study at any time with no penalty themselves or

their healthcare or insurance plans/benefits. In the event of safety concerns and/or due to the participant having exceptional difficulties with completing the questionnaires, the PI may decide to withdraw the participant from the study.

11. PRIVACY AND CONFIDENTIALITY

For this study, we will ensure the separation of de-identified participant data from protected health information (PHI) by storing data in separate locations. De-identified data will be stored using secure, password-protected software hosted on HFHS servers. All participant information will be referenced using participant identification numbers. De-identified participant responses to study measures will be collected and stored using REDCap, a software toolset and workflow methodology for electronic collection and management of data. Only the investigators/authorized staff will have access to the REDCap database. We will only keep a record of number of screenings completed and reasons for ineligibility.

We will need to collect names and demographic information for participants who complete consent. Once collected, data will be de-identified. The file containing the information that links participant names to their IDs will again be stored in password-protected files on the HIPAA compliant, secure REDCap file. Only investigators will have access to this file. The key linking identifiable information to the participant ID will be destroyed five years after publication of study results.

Once data are collected, all data will be de-identified, i.e. names will be removed and participants will be assigned ID numbers.

As part of the informed consent process, participants will be advised that they may decline to answer any questions. This will provide participants with the assurance of confidentiality around sensitive personal information relating to substance use and mental health. All personnel working on the project will be educated about the importance of respecting participants' rights to confidentiality. Investigators will all complete and maintain ethical and CITI training. All study personnel will be appropriately trained in the ethical conduct of human subjects' research.

Study files will be maintained until five years after the publication of study results in line with the guidelines of the American Psychological Association.

Due to Michigan law, we will disclose to the appropriate individuals and/or authorities any information that comes to our attention concerning child abuse or neglect, or thoughts of harm to self or others, or if a court of law ensures, a subpoena for the research records.

Important HIPAA Concerns

We will not be accessing electronic medical health records; we will, however, be collecting PHI on our patient locator form, demographics in our baseline and information to provide incentive through the ClinCard software.

We will collect and use:

- Name
- Address
- Telephone Number
- Email address
- Demographics

We may release this information to the following people:

- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Henry Ford Health Systems Institutional Review Boards (IRB)

No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use or sent outside of HFHS.

12. DATA AND SAFETY MONITORING PLAN

All research staff (including community liaisons) will complete relevant training in the protection of human subjects. Being proximally located to the data collection site, Dr. Felton will ensure that all participants meet inclusion/exclusion criteria and are appropriate for inclusion in the study. Data will be monitored on an ongoing basis and reviewed with the PIs at regular intervals. As data will be entered electronically, we do not foresee any concerns with inconsistent responses; however, should this problem arise, research staff will review all entries and determine a resolution.

All participant data and records will be maintained in a secure location accessible only to project staff. All data files will be stored under a randomly-assigned subject number and no identifiable information will be included in participant files. Consent forms and other documents with identifiable information will be kept in a separate, secured location. Any computers containing electronic data files will be password-protected and accessible only by study personnel. Only the PIs and the database administrator will have access to the data. Analyses will be conducted only after all data is collected, deidentified, and cleaned, thus limiting the possibility of deidentification. Any findings shared with community stakeholders will be done in aggregate and reflecting mean-level trends. We will also utilize the Certificate of Confidentiality provided by NIH to protect against requests to disclose sensitive research information, within the bounds of the law.

Adverse Events (AEs) and Serious Adverse Events (SAEs), as defined by the DHHP Office of Human Research Protections, will be monitored by the PIs Felton. AEs will be recorded by research staff on an AE form and discussed by the PIs during regularly scheduled meetings. The PIs will then prepare a written report for submission to the HFHS IRB and the appropriate NIH program officer. The report will include information regarding whether these events were expected or unexpected, the severity of the event, a brief narrative of the event, and a determination regarding any causal connection between the event and the ongoing research study. Any such events will also be included in the annual progress report send to NIH. In the unlikely event an SAE were to occur, research staff will alert the PI immediately. Subsequent reports to the HFHS IRB and NIH will be completed within 24 hours. The

expedited notice will be followed by a detailed report regarding the event as soon as possible.

All reports regarding events listed above will include study details (e.g. the title and grant number of the study and PI name), details of the event (date of occurrence, date that the MPIs became aware of these concerns), a detailed description of the event (including its impact on the participant), a detailed description of any steps taken to address the event, an attestation (including dates) that all required individuals/boards (including the HFHS IRB) have been notified, and any changes to the protocol or procedures that are proposed or implemented to prevent future occurrence of similar events.

This plan will also be reviewed by the Community Advisory Board, which will provide additional feedback to ensure the study team is addressing community-specific concerns regarding data and safety monitoring.

13.QUALIFICATIONS OF THE INVESTIGATOR(S)

Dr. Felton is an Associate Scientist at the Center for Healthy Policy & Health Services Research in Henry Ford Health Systems. She earned her PhD in child clinical psychology from Vanderbilt University with a minor specialization in quantitative methods. Her program of research centers on identifying risk factors for the onset of substance use in children and adolescents (e.g. Felton et al., 2015) as well as examining the role of early environmental and parenting factors associated with the trajectory of drug and alcohol use over time (e.g. Felton et al., 2020). She has specific expertise in assessment, research design, and data modeling techniques, having served as the PI, Co-I, or statistical consultant on a number of NIH-funded grants and published over 65 manuscripts and book chapters on the development of vulnerabilities to mental and behavioral health problems and targeted preventative interventions to reduce these risk factors.

14.REFERENCES

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