Full Committee Review ☐
Expedited Review ☐

MONTANA STATE UNIVERSITY
Institutional Review Board Application for Review
(revised 06/01/15)

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Application Number: Approval Date:
Disapproved: IRB Chair's Signature:

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Date:

I. Investigators and Associates (list all investigators involved; application will be filed under name of first person listed)

NAME: Dr. Katey Tuchscherer Franklin, PhD, LCPC TITLE: Addiction Counseling Program Director
Principal Investigator
DEPT: Health & Human Development PHONE #: (406) 570-6056
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DATE TRAINING COMPLETED: ___2018_____

SIGNATURE (PI or ADVISOR): _____

NAME: Dr. Mark Schure, PhD TITLE: Associate Professor, Community Health
Scientific Advisor
DEPT: Health & Human Development PHONE #: (406) 994- 3248
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DATE TRAINING COMPLETED: ____10/2018_____

Do you as PI, any family member or any of the involved researchers or their family members have consulting agreements, management responsibilities or substantial equity (greater than $10,000 in value or greater than 5% total equity) in the sponsor, subcontractor or in the technology, or serve on the Board of the Sponsor? _____ YES ___X__ NO

If you answered Yes, you will need to contact Kellie Peterson, Legal Counsel-JD at 406-994-3480.

II. Title of Proposal:
A feasibility study for implementing and evaluating an Internet-based cognitive behavior therapy intervention in school settings and its impact on adolescent mental and behavioral health

III. Beginning Date for Use of Human Subjects: **September 1, 2020**

IV. Type of Grant and/or Project (if applicable)
Research Grant: **X**
Contract:
Training Grant:
Classroom Experiments/Projects:
Thesis Project:
Other (Specify):

V. Name of Funding Agency to which Proposal is Being Submitted (if applicable): **Center for American Indian and Rural Health Equity (CAIRHE) - National Institute of Health (NIH)**

VI. Signatures

Submitted by Investigator
Typed Name: Dr. Katey Tuchscherer Franklin, PhD, LCPC

Signature:
Date: June 1, 2020

VII. Summary of Activity. Provide answers to each section and add space as needed. Do not refer to an accompanying grant or contract proposal.

A. RATIONALE AND PURPOSE OF RESEARCH.
iCBT and Y-T will be used interchangeably throughout document

Our research will examine the acceptability and efficacy of an Internet-based Cognitive Behavior Therapy (iCBT) intervention called Youth Thrive (Y-T). The Y-T program is not a counseling treatment intervention for participants with a high level of mental health acuity; it is a preventative program for a normative adolescent population which teaches mental and behavioral health resilience and adaptive coping strategies for normative stress from a CBT framework**.** As this is a feasibility and pilot study, we will conduct a process analyses of study implementation in school community settings. We will be working with select rural Montana school systems of which we already have established trusting and collaborative relationships with. **As a pilot feasibility study, we aim to understand how best to partner with school communities to implement Y-T programming, examine youth participants' engagement and experience with the online program, and understand trends in behavioral health data acquired with self-assessments (participant's experience of depressive and anxiety symptomology and addictive attitudes and behaviors). This research is expected to significantly advance our understanding of the integration of and potential impact of iCBT interventions designed to teach behavioral health awareness and skills for adolescents in school communities in rural Montana.**

Stressors and Other Risk Factors for Mental and Behavioral Health Issues Among Rural Adolescents
Adolescence is widely regarded as a key developmental stage in which youth experience dramatic physical and cognitive changes that also greatly influence their socioemotional wellbeing.[11] There are commonly known types of stressors that rural adolescents experience including academics, peer pressure (bullying, relationships problems, etc.), family issues (interpersonal violence, substance abuse, loss, etc.), and intrapersonal conflicts (self-esteem, personal expectations, etc.).[12] Our findings from several adolescent focus groups in rural Montana school communities confirmed these same types of stressors but also indicated how the cell phone culture has added to the list of stressors and increased feelings of isolation and peer pressure.[13] Those who report a greater number of these types of stressors also report experiencing greater depression symptom severity,[12] which places these adolescents at increased risk for substance use, self-harming, and other negative coping behaviors,[13,14] all known risk factors for increased depression symptoms, substance use, and other health- and academic-related problems in later adolescence and early adulthood.[15,16]

Mental and Behavioral Health Among Rural Adolescents.
Mental health and mental health care access remain a high priority for Rural Healthy People 2020.[17] Between 1996 and 2010, suicide rates among youth have substantially increased with nearly two-fold the rate among rural youth compared to urban youth,[18] suggesting greater prevalence of mental health issues and greater access to suicide means in the rural populations. Research has also demonstrated greater cumulative risk among rural youth compared to urban youth,[19] leading to higher rates of substance use and abuse among this population. For example, recent separate analyses of the National Surveys on Drug Use and Health found that rural adolescents have greater alcohol and methamphetamine use, and prescription opioid misuse compared to their urban counterparts,[20-22] and the more rural the greater prevalence of use.[22] In Montana, 36.7% of Montana adolescents report experiencing depression symptoms on a regular basis; 23.4% seriously considered suicide and 19.5% made a plan to attempt suicide.[3]

Mental and Behavioral Healthcare Access Challenges in Rural Communities.
There still exists an unmet need for mental and behavioral health resources for adolescents living in rural communities.[23] In rural communities, there are personal, environmental, and systemic reasons for challenges to seeking and obtaining adequate care for mental and behavioral health.[24] Rural barriers include lack of accessibility and availability of services as well as the acceptability of those services.[25] Accessibility and availability barriers include lack of services, lack of practitioners, lower use of evidence-based practices, and greater distance to care. For example, outpatient substance use treatment services are almost four times less available in rural hospitals (12.1%) than urban hospitals (43.7%).[26] Rural adolescents also perceive they have less access to school-based mental health services compared to their urban counterparts (65% compared to 71%).[27] Acceptability barriers include lack of privacy and lack of culturally appropriate

treatment. Due to rural residents' negative perceptions toward treatment of mental illness, accessing care becomes an issue for individuals living in small rural towns.[28]

To reiterate, this is a pilot feasibility study, which aims to understand how best to partner with school communities to implement Y-T iCBT programming in efforts to increase access to mental and behavioral health resources, examine youth participants' engagement and experience with the online program, and understand trends in behavioral health data garnered in assessment processes (experience of depressive and anxiety symptomology and addiction behaviors). Again, this research is expected to significantly advance our understanding of the experience and potentional impact of iCBT interventions designed to teach behavioral health skills for adolescents in rural Montana**.**

The questions we seek to answer are:

1. **How do we best partner with school communities to implement the Y-T program? (Aim 1, feasibility)**
2. **What are youth participants experience of the Y-T program? (Aim 2, process analysis from focus groups)**
3. **How does the Y -T program impact participant's experience of depressive and anxiety symptomology and substance use/addictive behaviors**? **(Aim 3)**

B. RESEARCH PROCEDURES INVOLVED. Provide a short description of sequence and methods of procedures that will be performed with human subjects. Include details of painful or uncomfortable procedures, frequency of procedures, time involved, names of psychological tests, questionnaires, restrictions on usual life patterns, and follow up procedures.

Objective: Employ a mixed-methods study design with three complementary research components in this pilot feasibility study to examine the Y-T program implementation process in school communities (Aim 1), understand participant experience and engagement with the Y-T program (Aim 2), and the impact of the Y-T iCBT intervention designed for adolescents to address depression and anxiety symptomology and addictive behaviors (Aim 3). As part of this pilot feasibility study, we will track institutional processes, policies, and obstacles that impact the implementation and evaluation of the Y-T program. These data will inform the future dissemination, collaboration and implementation of such interventions in school settings. We will conduct several focus groups to ascertain the acceptability and user engagement experience to understand the qualitative experience of the iCBT intervention with youth participants. We will provide access to the iCBT intervention and collect self-report data on outcomes of depression and anxiety (**Beck's Youth Inventories- Second Edition)**, and substance use behaviors **(Adolescent Substance Abuse Subtle Screening Inventory)** at baseline and 4, 8, 12, and 16-week time periods at two separate school sites. The proposed research design is a 4- to 16-week waitlist control group model.

- **Dependent variable(s):** School Community implementation process, participants' experience of and engagement with Y-T program, and behavioral trends of participants' experience of depressive and anxiety symptomology and addictive behaviors/attitudes
- **Independent Variable**: Implementation process in school community, and participation in online Y-T iCBT program which teaches skills pertaining to wellbeing, depressive and anxiety symptomology, coping strategies and addictive behaviors.

Intervention: iCBT Youth Thrive (Y-T) program

Y-T is an online, innovative, non-synchronous connect iCBT program for depression and anxiety that distills best practices from Cognitive Behavioral Therapy and delivers them through a rich, structured and guided curriculum. *Thrive* emulates CBT through the use of didactic video segments, interactive tools, and sophisticated algorithms that dynamically adjust the individual's course through the program. Y-T uses approximately hundreds of videos, averaging eighty seconds in length, to deliver content. Videos explain CBT concepts, demonstrate skills, provide feedback and recommendations, and portray actual case histories of individuals who used CBT to combat depression and anxiety. Scripts are written at the 6.5 grade reading level. The use of video appears to improve participant engagement, a shortcoming seen in earlier iCBT programs.[39]

Cognitive behavior therapy (CBT) is a structured form of psychotherapy that seeks to replace dysfunctional thought patterns and behaviors with healthier ones. It does so by challenging negative thinking patterns and identifying areas for improving behaviors. By changing the interaction of thinking and behaviors, persons are more likely to feel

better about themselves (see Figure 1). Because CBT is structured, it can be emulated using software in the form of iCBT programs.

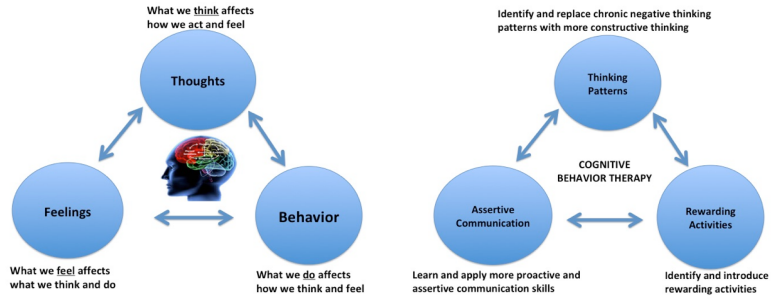

Figure 1. Conceptual Framework for CBT with depression and anxiety

An individual's path through the Y-T is guided by more than 100 algorithms that evaluate the individual's profile to determine which instruction, feedback, or assignment to deliver next. As the individual progresses through Y-T, algorithms make increasingly specific recommendations. The Y-T adolescent intervention includes four "modules", each based on a different CBT technique and subsequent psychoeducational content. Y-T recommends a module to each participant based on their salient symptoms. While youth participants may use all modules, the program encourages adherence to a single module. Y-T's developmentally appropriate instructional modules are:

Assertive Communication, based on the social skills training technique. In Assertive Communication, individuals learn how to speak with others clearly and confidently.

Constructive Thinking, based on the CBT cognitive restructuring technique. In Constructive Thinking, individuals learn to spot unreasonable thinking patterns that may be affecting their mood and how to replace them with more constructive thoughts.

Rewarding Activities, based on the behavioral activation technique. In Rewarding Activities, individuals learn to overcome challenges preventing them from engaging in hobbies, social activities, and exercise.

Comorbid conditions (mental health + substance use) and Addictive Behaviors. This module focuses on learning about underlying stressors, the emergence of maladaptive coping strategies or avoidant addictive behaviors, and how to replace these behaviors with more sustainable coping behaviors.

The research team specifically designed and customized the Y-T program to make it developmentally appropriate to youth ages 13-18 years old. To do so, the research team conducted in-depth youth focus groups in high school communities in urban, rural and frontier Montana. Discussion questions posed to the adolescent focus groups included identification of relevant stressors in their lives, perception of available behavioral health resources, attitudes/thoughts about addiction, and perception of viability and usability of an online behavioral health program like Youth Thrive. Qualitative data garnered from youth focus group was coded, organized and used in the design and creation of the actual content of the Youth Thrive program. Additionally, the research team hired a licensed, doctoral-level adolescent counselor as content expert to inform and review all scripts developed and used in the Youth Thrive program. *Please access video links to Y-T program provided by MSU research team for video clip from the program.*

The module topics are assertive communication, constructive thinking and rewarding activities, the actual content and language are developmentally appropriate and relevant to adolescents. To illustrate, identified stressors in the Youth Thrive program are peer pressure and/or isolation, social media influences, impact of family system stressors, and school-based stressors, whereas the adult version of Thrive identifies adult stressors as financial, career, family, and agricultural stressors. Additionally, the Y-T program includes a developmentally appropriate educational addiction-specific information. This piece provides education about normative (cognitive, physical, emotional and social) responses to stress, identification of common stressors in adolescence, and ways of coping with stressors. This content identifies coping strategies that are adaptive to sustainable wellbeing and also coping strategies that are maladaptive to wellbeing, and it educates participants about hazards of practicing maladaptive coping strategies. This content also

provides developmentally appropriate information regarding maladaptive or avoidant coping strategies such as potential behavioral process addictions (overuse of electronics, excessive videogaming, preoccupation with social media, over-exercising, shopping, binging, gambling, etc.). This content also identifies substance abuse as a maladaptive coping strategy for normative adolescent stress.

Y-T also provides safeguards and guidance if the program is not working effectively. For example, if the user indicates no improvement, a scripted message will inform them to consider switching modules or to get personalized help outside the program. If the user indicates having thoughts of suicide, the program automatically asks whether the user can keep her- or himself safe and to seek immediate help if they cannot. This program is innovative and the first known type of a tailored interactive iCBT program to address comorbid conditions for adolescents.

The Y-T program and assessments will be implemented in health class during school hours. As it is a non-synchronous connect iCBT program that can be used independently by the students, the school faculty do not need to facilitate lessons plans. Participants will use school computers to engage the Y-T program. If they choose to, participants may also access the online program outside of school hours on their own electronic devices.

Study Population. We will partner with select Custer and Park County (MT) school communities (Miles City and Livingston) to recruit approximately 100 adolescents aged 13-18 years. Currently, committed schools intend to include the intervention as part of the Freshman and Sophomore health enhancement class curriculum. Students have the opportunity to opt out of the research portion (participation in study assessments and focus groups) of the Y-T program.

Inclusion criteria for this study include: 1) being aged 13-18 years, 2) fluent in English, 3) have access to a working email account, and 4) have regular access to broadband Internet in school setting.

Incentives: Participants who complete all study assessments will receive a $50 Amazon gift code.

Research Design

As this is a feasibility and pilot study, we will employ a mixed-methods study design with three complementary research components to understand the experience and impact of an iCBT intervention designed for adolescents to address depression and anxiety symptoms and reduce addictive behavior tendencies. We will conduct pre- and post-assessments to measure the Y-T program's quantitative impact and conduct several qualitative focus groups to ascertain the acceptability and user engagement experience to understand the qualitative impact of the iCBT intervention. Furthermore, we will track institutional processes and policies that impact the implementation and evaluation of the pilot study. These qualitative data will inform the future dissemination and implementation of such interventions in school and behavioral health care settings.

Data Collection.

Qualitative Process Data (Aim 1). We will collect data on institutional (school) policies, procedures, and events that facilitate or hinder study implementation. The PI will schedule periodic meetings with each of the institutional authorities to gauge any challenges and opportunities for study implementation. We will track institutional processes, policies and barriers that impact the implementation and evaluation of the pilot study. These qualitative data will inform the future dissemination and implementation of such interventions in school and behavioral health care settings.

Qualitative Data (Aim 2). We will conduct several qualitative focus groups with randomly selected youth participants at both sites to ascertain the acceptability and user engagement experience to understand the qualitative experience of the Y-T intervention. We utilize best practice in conducting online focus groups and will develop an open-ended focus group guide and facilitate a number of distance (via Webex or Zoom) focus groups at each of the study administration sites. Focus groups will be audio-recorded and transcribed for analysis. Questions will examine acceptability, program engagement, and qualitative experiences of using the program. Participants will include a subset of the quantitative study phase (see focus group guide). Two- three focus groups will be conducted at each research site, and last 30 minutes to an hour.

Quantitative Data (Aim 3). We will also engage a preliminary group (school)-randomized waitlist-control group study design with the two identified sites to collect self-report data on outcomes of depression, anxiety, and substance use behaviors at baseline, 3-week, 6-week, and 8-week time periods (4 times over an 8-week intervention period). The MSU research team will orient school staff to the behavioral health assessment tools used in study, and school community protocols identified should participant safety issues emerge. *It is important to note that we have explored the potential for a randomized waitlist controlled study design, and our school community partners have expressed some concern that it would be difficult to initially implement this type of design.. In the event that we are unable to perform a WLC design, then we will evaluate baseline, 3-, 6- and 8-week outcomes only with no group comparisons.*

Analysis Plan.
Process Analysis (Aim 1). At the end of study implementation, the research team will meet to discuss and summarize all process data that are collected; we will also conduct monthly meetings with key school personnel.

Qualitative Analysis (Aim 2). We will conduct content analysis on each of the focus group transcripts, using multiple coders for verification and consensus-building.

Quantitative Analysis (Aim 3). Analyses will be conducted using SAS or SPSS statistical software using a mixed-model ANCOVA, with regression adjustment for the baseline depression scores for both the primary outcome measures using the BYI-2 and the secondary outcome measures form the Adolescent Substance Abuse Subtle Screening Inventory (SASSI-A2). The intent of this analysis is to understand the effects of the iCBT intervention on each outcome measure (anxiety, depression, and substance use/abuse), and to explore differences by participant characteristics.

Baseline and Intervention Phase Quantitative Assessment Measures:

- **Beck's Youth Inventories- Second Edition (BYI-2):** The BYI-2 measures symptoms/experiences of depression, anxiety, anger, self-concept, and disruptive behavior. The BYI-2 aligns with co-occurring symptom criteria specific to anxiety and depression from the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR). This assessment takes about 10 minutes to administer.
- **SASSI-A2 (Adolescent Substance Abuse Subtle Screening Inventory):** The SASSI-A2 helps identify the probability of substance dependence and substance abuse disorders in adolescents and provides clinical insight into family and social risk factors, level of defensive responding, and consequences of substance misuse. The SASSI-A2 aligns with diagnostic symptom criteria specific to addiction and substance use disorders from the DSM-IV-TR. This assessment takes approximately five minutes to administer.

The evaluation team (Drs. Katey Franklin and Mark Schure, CAIRHE staff) will review all data results in sensitive timeframes. Dr. Katey T. Franklin, Principal Investigator of the evaluation, will work closely with MSU's Office of Sponsored Programs and IRB to ensure the safety and confidentiality of research participants, and ensure responsible conduct of research.

The *Standards for Educational and Psychological Testing* published by the American Educational Research Association (AERA), American Psychological Association (APA), and the National Council on Measurement in Education (NCME) maintain strict qualification regulations for assessment administration. A central principle of professional test use is that individuals should use only those tests for which they have the appropriate training and expertise (classifications A-C). Dr. Franklin is an approved classification "C", the highest level of test administration classification.

C. DECEPTION – **At no point will deception be used in this study. The fore-mentioned Youth-Thrive program is designed to increase adaptive coping strategies in wellbeing and behavioral health, and the youth participants (and their guardians) will be informed of that.**

D. SUBJECTS
1. Approximate number and ages
How Many Subjects: **100**
Age Range of Subjects: **13 -18 years old**
How Many Normal/Control: **50**
Age Range of Normal/Control: **13- 18 years old**

2. Criteria for selection: Participants are enrolled in Montana Public Education at either Park County **High S**chool in Gardiner, Montana or Custer County High School in Miles City, Montana. Youth participants will be currently enrolled in a Health Enhancement class where Youth Thrive will be implemented and delivered as part of the Health Enhancement education curriculum.

3. Criteria for exclusion: N/A; lack of parental/guardian consent and/or participant assent for participation in research study.

4. Source of Subjects (including patients): Existing, enrolled students at Park County and Custer County (Miles City) High Schools. Please see included letters of support from school districts.

5. Who will approach subjects and how? Explain steps taken to avoid coercion. School officials will be initial point of content regarding participation in the research study. As part of the informed consent process, parents/guardians will have option to opt out on behalf of their minor in terms of participation in the research aspect of the Youth Thrive program delivery. Additionally, students will be provided an informed consent and provide their assent to participation as well.

6. Will subjects receive payments, service without charge, or extra course credit? **Yes** or No
(If yes, what amount and how? Are there other ways to receive similar benefits?) The Y-T program will be delivered as part of the Health Enhancement course, students will receive participation grades and credit in the high school course needed for graduation. Additionally, students are eligible to receive a $50 gift card to Amazon if they complete all research assessments (BYI-2 and SASSI) and, if randomly selected **to** participate in focus groups.

7. Location(s) where procedures will be carried out. Given travel restrictions and social distancing directives because of COVID 19, all planning with education communities and administrative teams will occur via WebEx and Zoom. The Youth Thrive iCBT program and assessment measures are delivered entirely online. The data analysis and interpretation processes will either occur on the Montana State University campus or via WebEx/Zoom with the research team.

E. RISKS AND BENEFITS (ADVERSE EFFECTS)

1. Describe nature and amount of risk and/or adverse effects (including side effects), substantial stress, discomfort, or invasion of privacy involved.
The nature of the behavioral health assessments which assess specifically for depressive, anxiety, and addictive symptomology may cause emotional discomfort with some of the youth participants. Given the training provided to school staff and supportive nature of the school community, school staff may facilitate a group debrief after the brief assessment period. Moreover, assessment results will be promptly scored and interpreted by MSU research team. If any youth participants' score in the "severe" categories for anxiety, depression and/or addictive behaviors, the research team will notify the school authority. Each school has in place a protocol for notifying parents/guardians when students are identified as high risk; these protocols assure that referrals will be made to behavioral health clinicians in their community.

2. Will this study preclude standard procedures (e.g., medical or psychological care, school attendance, etc.)? If yes, explain. **No.**

3. Describe the expected benefits for individual subjects and/or society. **Participants may benefit from the experience of actively participating in experimental research. The Y-T program is not a counseling treatment intervention, it is a preventative program which teaches about resiliency, mental and behavioral health, and coping strategies for normative stress from a CBT perspective. Participants may benefit from learning Y-T program information and practicing skills. Also, the researchers intend to use**

the research results to inform best practice in the creation and delivery of curriculum aimed at increasing adaptive coping strategies in mental and behavioral health, decreasing symptomology of anxiety and depression, and decreasing permissive attitudes toward addictive behaviors and substance use.

F. ADVERSE EFFECTS

1. How will possible adverse effects be handled?
   As aforementioned, the nature of the behavioral health assessments which assess specifically for depressive, anxiety, and addictive symptomology may cause emotional discomfort with some of the youth participants. School community staff are prepped and trained as part of their education training programs in how to encounter and talk with youth in distress. Moreover, school staff will have participated in an appraisal orientation prior to the administration of assessment tools with Dr. Franklin—they will understand the nature of the assessments and be prepared to discuss with and support youth participants. Additionally, assessment results will be promptly scored by the MSU research team (within 24 hours of administration). Safety protocols and reporting procedures will be established at each research site prior to the delivery of Y-T program and assessment tools. If any youth participants' score in the "severe" or clinically significant categories for anxiety, depression and/or addiction symptomology, parents/guardians will be notified. The researchers will notify the corresponding school authority, who will then implement existing school policies towards parental notification and referrals. Appropriate referrals will be made to low/no-cost behavioral health clinicians in the community.

2. Are facilities/equipment adequate to handle possible adverse effects? **Yes** or No
   (If no, explain.)

3. Describe arrangements for financial responsibility for any possible adverse effects. **No arrangements have been made.**

G. CONFIDENTIALITY OF RESEARCH DATA

1. Will data be coded? **Yes** or No

2. Will master code be kept separate from data? **Yes** or No

3. Will any other agency have access to identifiable data? Yes or **No**
   (If yes, explain.)

4. How will documents, data be stored and protected?
   Locked file: **Yes**
   Computer with restricted password: **Yes**
   Other (explain):

VIII. Checklist to be completed by Investigator(s)

A. Will any group, agency, or organization be involved? **Yes** or No
   Yes, please see letters of support from Custer and Park County educational communities

B. Will materials with potential radiation risk be used (e.g. x-rays, radioisotopes)? Yes or **No**

1. Status of annual review by MSU Radiation Sources Committee (RSC). Pending or Approved
   (If approved, attach one copy of approval notice.)

2. Title of application submitted to MSU RSC (if different).

C. Will human blood be utilized in your proposal? Yes or **No**
   (If yes, please answer the following)

1. Will blood be drawn? Yes or **No**
   (If yes, who will draw the blood and how is the individual qualified to draw blood? What procedure will be utilized?)

2. Will the blood be tested for HIV? Yes or **No**

3. What disposition will be made of unused blood? **n/a**

4. Has the MSU Occupational Health Officer been contacted? **n/a**

D. Will non-investigational drugs or other substances be used for purposes of the research? Yes or **No**

E. Will any investigational new drug or other investigational substance be used? Yes or **No**
   [*If yes, provide information requested below and one copy of: 1) available toxicity data; 2) reports of animal studies; 3) description of studies done in humans; 4) concise review of the literature prepared by the investigator(s); and 5) the drug protocol.]*

F. Will an investigational device be used? Yes or **No**
   (If yes, provide name, source description of purpose, how used, and status with the U.S. Food and Drug Administration FDA). Include a statement as to whether or not device poses a significant risk. Attach any relevant material.)

G. Will academic records be used? Yes or **No**

H. Will this research involve the use of:
   Medical, psychiatric and/or psychological records Yes or **No**
   Health insurance records Yes or ***No***
   Any other records containing information regarding personal health and illness Yes or **No**

   If you answered "Yes" to any of the items under "H.", you must complete the **HIPAA worksheet**.

I. Will audio-visual or tape recordings or photographs be made? Yes or **No**

J. Will written consent form(s) be used? (Yes or No. If no, explain.) (Please use accepted format from our website. Be sure to indicate that participation is voluntary. Provide a stand-alone copy; do not include the form here**.) YES. Participant Assent form, and Parent/Guardian Informed Consent forms included in IRB application package. Importantly, Participation Assent form will be read aloud (by staff) to students in Health Enhancement class at onset of research study.**