

## Supplement A

### DRAFT IRB PROTOCOL CONCERNING THE PROTECTION OF HUMAN SUBJECTS

This Human Subjects Research meets the definition of a clinical trial.

#### A. Risks to Human Subjects

A. 1. Human Subjects Involvement, Characteristics, and Design. Rural youth suicide represents a major source of mental health inequity in the United States (US) with suicide rates among rural youth almost double those of their urban peers. This is especially evident in Montana (MT), as the suicide rate among 12- to 18-year-olds (17.9/100,000) well exceeds the national average (6.4/100,000). The proposed pilot study for the universal suicide prevention program, Youth Aware of Mental Health (YAM), will expand upon previous research with European youth by evaluating the feasibility and acceptability of YAM-TE, a novel and, we expect, more sustainable approach for rural schools, and by generating pilot data on the effectiveness of YAM-TE as compared to the traditional YAM delivery method using external, non-school affiliated instructors (YAM-EXT) among youth in US rural schools.

We will employ a noninferiority, randomized trial (course sections within each school) to evaluate the implementation of YAM-TE (experimental group) with rural youth in MT and collect pilot data about its effectiveness compared to the traditional YAM delivered by trained external, non-school affiliated instructors (YAM-EXT; control group). We will work with each school districts to identify teachers in partnering schools willing to be trained, implement, and provide structured survey (YAM Training, Teaching, and Impact of YAM on the school) and checklist (fidelity, safety) data about YAM-TE. In addition, we will identify and hire external instructors to be trained, implement, and provide structured survey (YAM Training, Teaching, and Impact of YAM on the school) and checklist (fidelity, safety) data about YAM-EXT. All 9<sup>th</sup> grade students ( $n = \sim 1300$ ) will participate in the YAM-TE or YAM-EXT program as part of their health curriculum during their regular class period. As such, all parents will be notified of their child's participation in the YAM-TE or YAM-EXT program, but will not require

informed parental consent to receive YAM in the school setting. We will require parental consent for collecting research data from youth.

Inclusion criteria for adult participants (teachers, external instructors) will require being currently employed at one of the participating schools or hired to deliver YAM as an external instructor, and willing to be formally trained in YAM instruction. We will invite and train 4 teachers at each school (total trained=16) to ensure adequate staff in the event of illness or other unforeseeable events. We anticipate needing to hire 8 external instructors. We will ask both YAM teachers and external instructors to provide data on feasibility, fidelity, and safety, and both TS and EXT thus are considered research participants in the proposed pilot study.

We will invite all 9<sup>th</sup> grade students (n = ~1300) to participate in the proposed pilot research. We expect a minimum response rate (receipt of both parental/guardian consent and student assent) of 55%, for a minimal total study sample of ~ 715 students at baseline (about 50% of whom will be in the experimental condition of YAM-TE). We expect a 10-15% attrition rate from baseline to 12-month follow-up with ~607 to 643 students participating again at 12-month follow-up. To be included in the study, we must receive signed caregiver consent (e.g., parent) and assent from the youth.

**Different Cultural Backgrounds.** Most Montana residents and students in the participating schools are White (~89%); Native American and Hispanic youth represent the largest minority group, with between 6-8% youth enrollments at the participating schools. Based on local community demographics, we expect parents and teachers to be 85% White; one of the two external trainer/YAM instructors is Native American. We will make all possible efforts to recruit and include minority participants in the focus groups, implementation, and evaluation of YAM (students, parents, teachers, and external instructors). Moreover, we will require that all instructors (teachers and external) and research staff participate in cultural diversity and ethical standard training.

A.2. Sources of Materials. We will use structured and semi-structured survey questions to collect information from students, teachers, and external instructors for this study.

A.3. Potential Risks. No major risks are associated with the proposed research. We will inform all participants of the purpose of the study, involved YAM intervention strategies, and types of assessments. We will obtain written informed consent from teachers and external instructors, and parental consent for youth and youth assent to participate in the youth survey assessments (pre-intervention, post-intervention, 12-month follow-up). There are the following minimal potential risks associated with participating in the youth survey: The personal and sensitive nature of survey questions (e.g., youth mental health, suicide) may result in students becoming uncomfortable or slightly distressed. We will notify the participants in the informed consent and assent that they may experience such feelings. Although these feelings are typically short-lived and pose minimal risk to students, we will ensure that school counselors are available during the survey assessment to visit with students who become distressed. Students also will be informed that their participation is entirely voluntary and that they may stop taking the survey at any time without consequence.

## B. Adequacy of Protection Against Risk

B.1. Recruitment and Informed Consent. We will employ active consent procedures for recruiting and enrolling participants into the study. We will send a parental consent form and letter to all caregivers of 9<sup>th</sup> grade students via email and home with the students. The parental consent form and letter will inform caregivers that their child will be participating in the YAM program as part of the school's regular health curriculum. We will clarify in the consent (and student assent) form and letter that the child does not need to participate in the evaluation study of the YAM program to receive it. We will provide the caregivers with information about YAM, including 1) a brief description of the YAM program, 2) potential benefits and risks of participating in the YAM program, 3) description of the evaluation study portion of YAM, 4) an invitation for their child to participate in the evaluation of YAM,

and 5) how to access more information about YAM (link to YAM website, contract information for Kelley Edwards, the program coordinator). We estimate that the rate of return for parental consent of student participation will be approximately 55%, but as high as 65% if we send up to three reminder emails to parents who do not respond to the request for consent and wait 14 days for consent to be returned. Students whose parents have given consent will be approached in their regular health class and will be invited to participate in the evaluation study at baseline, post-YAM, and 12-month follow-up. For those students who assent to participate in the YAM evaluation study, data will be collected during their regular health class period the week before they begin the YAM program. We expect high student participation in the 12-month follow-up since the initial parental consent will be sought for both the baseline and follow-up assessment. We will make two follow-up attempts with students who missed class during the 12-month follow-up.

Our project manager, Ms. Kelley Edwards is a Montana native and former teacher with excellent connections to teachers in the participating schools. With support from the school principals, we will invite teacher study participation via email and direct contact. EXT will be hired on a part-time basis, conditional upon successful background check. EXT will be invited to participate in the post-YAM training questionnaire assessment and the post-YAM structured questionnaire. The research participation is voluntary.

B.2. Protection Against Risks. Participating students with signed parent consent and who assent to participate will complete the survey in a designated room in the school, while non-assenting student will remain with their teacher in the health class during the survey. We anticipate that the student's feelings of uncomfortableness or slight distress due to the personal and sensitive nature of the survey questions to be short-lived and typically students do not experience long-term consequences from completing the survey. In fact, we expect most of the students will benefit from a better self-understanding following completion of the survey. In addition, past studies have shown that asking

about suicide does not increase risk for self-harm [115,116] and the two questions we will ask student comes directly from a widely-used school assessment tool already given to students in the four participating schools [11]. The other survey measures also are widely used in child and adolescent research and no iatrogenic effects have been reported. Nevertheless, we will remind students that they can stop answering questions at any time without a negative consequence.

There are no reported or known risks to students who participate in the YAM program. However, the topics may be personal and sensitive in nature and the role-playing sessions may elicit uncomfortable or mildly distressed feelings in students. We will inform students of their right *not to* actively participate in the YAM discussions or role-playing sessions. YAM instructors (and assistants) will monitor student functioning (e.g., agitation, avoidance, resistance) over the course of the YAM program and will be trained to manage acute distress in the classroom. If the YAM instructor feels the student needs further help with acute distress, the YAM assistant will walk the student to the school counselor at the school. Moreover, we will provide all students with specific information about the “rules” of confidentiality in group settings and the respect the rights of their peers. In addition, YAM instructors will work with students to establish other rules to ensure respectful communication within the group.

All YAM instructors will be trained to identify and report “adverse events” within 24 hours to Ms. Kelley Edwards (YAM project manager) and study investigators using a structured YAM Documentation of Adverse Event form. We consider “adverse events” to be “any occurrence which disrupts a YAM session, causes concern for an Instructor or Assistant, or pushes beyond appropriate boundaries.” Examples of “adverse events” may range from a student crying or needing to leave the classroom to inappropriate behavior to bullying in the classroom to a school-wide disruption or crisis. As per the YAM training and implementation policy, we will encourage YAM instructors to use their best judgment and consultation with other YAM instructors and the investigative team to determine the best

course of action. If a student needs to leave the classroom, the YAM assistant will walk the student to the school counselor at the school.

B.3. Managing youth emergency cases. Parental consent and youth assent forms will specify that youth reporting suicidal ideation or behavior will be referred to the school counseling staff who will enact the school's protocols concerning supporting at risk students. All MT schools have such protocols, as per Department of Education policies. Youth are notified at the beginning of YAM that if any dangerousness is expressed (e.g., threat of harm to self or others), the YAM instructor (TE or EXT) will notify the school counselor or appropriate mental health back-up staff at the school. As part of the YAM training, instructors are taught how to respond to students who present with disruptive behavior or who express suicidal ideation or threats to safety of self or others. YAM instructors will work with school health, mental health, or counseling personnel to ensure that participating students' needs are met.

Emergency cases will be identified through affirmative answers to the two YRBSS items concerning suicidality: "During the past 12 months, have you ever seriously thought about killing yourself?" "Have you ever tried to kill yourself?" Study staff will audit student questionnaires within 24 hours of administration to determine whether any student has answered these items in the affirmative. Study staff will immediately contact the school mental health professional who will contact the students and link the student with mental health care services, if necessary. Students displaying low-level suicide risks but intermediate mental health problems will also be encouraged to seek mental health services.

If during YAM curriculum delivery there are disruptive students or students that leave the YAM course without YAM instructor permission, the instructor will notify the appropriate school staff and school will follow their discipline policy. If during or after YAM delivery, a student discloses information regarding another student or themselves imminent risk of harm, the school staff will follow their school policy regarding students who disclose possible risk of harm. YAM instructors will record these instances on the adverse events checklist.

The instructors will serve dual roles as the implementers of the YAM program and research participants. We will obtain signed informed consent from each instructor and explain the amount of time and effort associated with implementing YAM in the school and participating in the study assessments. As with other youth participants in the proposed pilot study, instructors will have the right to discontinue the survey without negative repercussions. Teachers and external instructors will participate in bi-weekly supervision meetings (separate for TE and EXT); these meetings will occur via video conference calls with a study trainer and provide an opportunity for TE or EXT to share any concerns or difficulties (including feeling stressed by occurrences in the classroom) they may have encountered while teaching the YAM curriculum. Additionally, TE or EXT may request a consultation call if urgent concerns arise between regularly scheduled supervision meetings. Brief summaries of the supervision calls will be documented and will be used to inform any modifications to YAM delivery or materials in the future large scale trial.

B.4. Confidentiality. We will use a Master List containing both a unique ID number and associated student's, teacher instructor's and external instructor's name and will take steps to ensure the confidentiality of the survey data. Specifically, the unique ID number will be included with the students', teachers', and external instructors' names on the Master List and will be used as the ID number in the complete deidentified aggregate data file used for study analyses. In addition, only the unique ID number will be present on the surveys. The hard copy of the Master List with identifying information (i.e., names) and associated unique ID numbers will be kept in a locked filing cabinet in the Project manager's office and as an encrypted electronic file on the Montana State University's Knox Folder password-protected server, which is maintained by MSU and only the PI, Co-I, and project manager will have access.

C. Potential Benefits of the Proposed Research to Human Subjects and Others

All study participants will gain knowledge about youth mental health, suicide risk, and positive youth development. Specifically, teachers and external instructors gain mental health literacy via the YAM training and learn about positive teaching strategies for how to engage youth in productive discussions or role plays. School teaching staff and external instructors will be compensated \$20.00 for completing the post-YAM structured questionnaire. Youth may benefit from the research by being able to share their perspective about the proposed research; youth may experience the opportunity to provide input as empowering. Youth will benefit from the prevention curriculum which teaches mental health literacy and resiliency skills. Students may benefit from participation in the outcome assessments by contributing to the advancement of knowledge about youth suicide prevention.

D. Importance of the Knowledge to be Gained

Youth suicide risk is an important public health concern and rural youth suicide is a major source of mental health disparity in the US. The proposed research is expected to inform refinement or adaptation of a school-based universal suicide prevention curriculum of proven effectiveness based on research in European youth, for implementation in rural high schools in the US. It addresses an important gap in the research literature because to date, few school-based universal suicide prevention studies have been conducted in the US, and research on rural youth and high school-aged youth is lacking. The proposed study will provide important feasibility and pilot effectiveness data that will be utilized the design a subsequent fully powered prevention study in schools across rural states in the US. We believe that the risks of discomfort to research subjects are largely outweighed by the societal benefits of the information to be gained from the proposed research.