



University of Missouri - St. Louis
Application for Full Review by the Institutional Review Board

Please supply (on numbered additional pages) the information requested below. Use the same Roman Numerals and capitalized key words to identify each section. Your responses should be concise.

I. Introduction

GENERAL PURPOSE

The Children's Advocacy Services of Greater Saint Louis (CASGSL) is a part of the Department of Psychological Sciences at the University of Missouri – Saint Louis. We recently received a grant from the Substance Abuse and Mental Health Services Administration (SAMHSA). The title of this research is "Foundations for Outreach Through Experiential Child Advocacy Studies Training" or more simply, *Project FORECAST*.

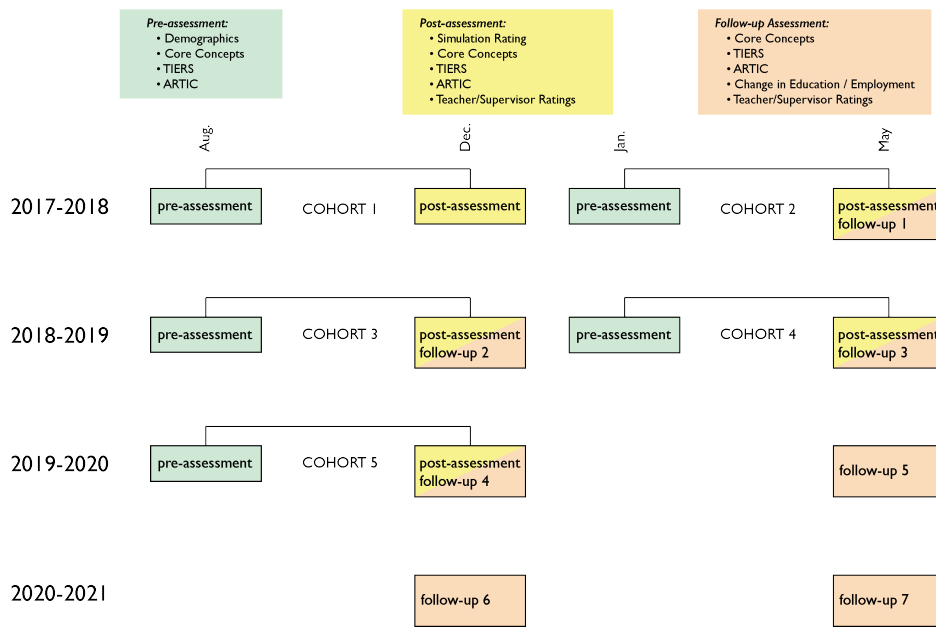
The overarching goal of FORECAST is to develop and evaluate problem-based learning simulations (PBL-S) that will be embedded into undergraduate and graduate-level Child Advocacy Studies (CAST) curricula. PBL-S activities provide students an immersive learning experience which involve role playing activities, identification of factual information presented in the case, and brainstorming potential hypotheses. PBL-S is a markedly different method of instruction than traditional lectures, requiring students to take an active part in the learning experience.

The simulations we have created for FORECAST aim to promote in students a greater sensitivity to the needs of children who have experienced trauma. We have carefully crafted our simulations to ensure that they will provide instruction in the National Childhood Traumatic Stress Network's *The 12 Core Concepts of Understanding Traumatic Stress Responses in Children and Families*. These are a "broad range of points that practitioners and agencies should consider as they strive to assess, understand, and assist trauma-exposed children, families, and communities in trauma-informed ways." Our simulations are also designed to promote students' acquisition of Trauma Informed Experiential and Reasoning Skills (TIERS), which are a collection of key competencies trauma-informed professionals should be able to demonstrate.

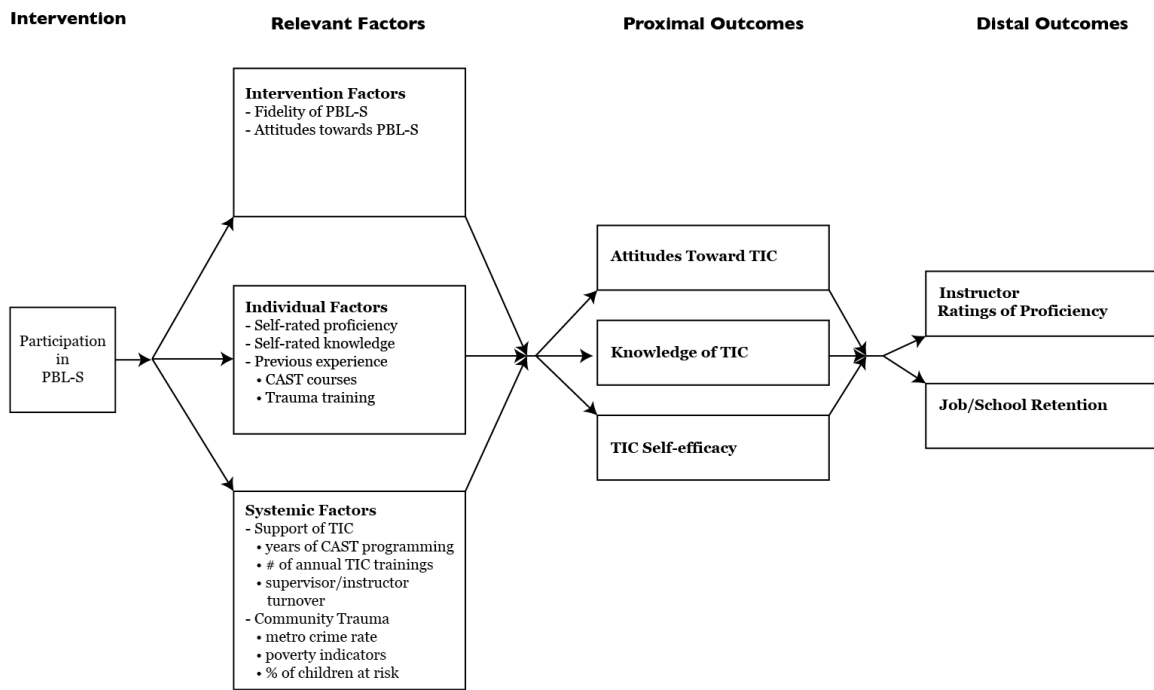
An important component of our SAMHSA grant is a series of Learning Communities for university professors of CAST courses. During these Learning Communities, participants will receive instruction for how to deliver our simulations. Essentially, our grant is enabling us to conduct a large-scale curriculum development and dissemination project. University professors across the country will be implementing our simulations and evaluating their students' acquisition of knowledge and skills through our accompanying assessments within their CAST courses. As part of the curriculum development process, we will gather data from all students in the participating instructors' classrooms at the beginning and end of the course. We will then supply all of the information collected from all the students to their instructor at the end of the term for the instructors' individual use in evaluating their students. As part of this process, students may elect to allow their assessment data to be used for research purposes. Therefore, although we will collect and transmit all student data to instructors, we will only retain in our research database responses from students who have consented to participate in our research. For the duration of the project, we will conduct bi-annual follow-ups of all research participants.

We will enroll five cohorts in this project. The participants of this project will be university professors and their associated CAST students. The size of each cohort will vary but will consist of a minimum of five universities, each with two CAST courses. If we anticipate the average class size to have thirty students, each cohort will have five professors and approximately 300 students for a total of 25 professors and 1,500 students across the duration of the project. We will use a rolling enrollment strategy in which universities in the cohort immediately following the active cohort will serve as controls.

Below is a schematic of our intervention and assessment schedule:



Below, is a schematic that provides an overview of our logic model and our expected outcomes.



HYPOTHESES and RESEARCH QUESTIONS

We predict that as compared to students at our control schools, students who participate in our interventions will:

- Demonstrate improved knowledge and attitudes towards trauma-informed care as well as higher self-rated efficacy at delivering trauma-informed care (as measured by the ARTIC),
- Be rated more proficient by their instructors,
- Demonstrate less secondary traumatic stress once they transition to their professional career (as measured by the ARTIC), and
- Have higher rates of job retention.

II. Methods

Describe the EXPECTED GROUP(S) (control, experimental, etc.) to be used. Give the NUMBER OF SUBJECTS anticipated for inclusion in each of the above groups. Outline the INCLUSION CRITERIA for subjects (justify the involvement of any of the special groups listed in the General Application, questions 5 or 6). Include how subjects will be recruited. Describe the ROLE OF SUBJECTS, including what they will be asked to do and whether deception will occur. Describe all MEASUREMENT PROCEDURES. Attach copies of any questionnaires, measurement instruments, or interview protocols to be used. Describe the EXPECTED DURATION of the subject's participation.

PARTICIPATING UNIVERSITIES

A number of universities across the country (including UMSL) have agreed to take part in *Project FORECAST*. We will provide CAST professors from participating universities detailed manuals, implementation guides, and curriculum materials which will facilitate their adoption of our Problem-Based Learning Simulation materials into their syllabi. All students in these classes will participate in the classroom activities. Participation in the research, however, will be completely voluntary.

This is a multi-year study that will have a total of five cohorts. We have reached out to a number of universities who have agreed to participate in this project. At this point in time, in addition to our instructors here at UMSL, we have formal agreements with six universities that will serve in our initial cohort. They are:

- a) Athens State University
- b) Culver-Stockton College
- c) Indiana University of Pennsylvania
- d) New Mexico State University
- e) University of Illinois- Springfield
- f) Northwest Arkansas Community College

As the project continues, and we enroll additional universities into our subsequent cohorts, we will submit modifications to this IRB application along with the Letters of Support. Our plan is to continue enlisting schools to first serve as controls and then transition them into the actual intervention. UMSL will serve as the IRB of record for this research project, participating universities will submit our IRB approval to their respective IRB committees.

MEASUREMENT PROCEDURES.

It is important to understand that data generated by this project will serve two purposes. First and foremost, we designed the assessments to reflect the content of our curriculum. Consequently, outcomes on these measures will facilitate instructor's evaluation of their student's performance in the class as well as providing feedback to the instructors to improve their own PBL-S implementation. However, because the project also encompasses a research component, we will also use the data to assess the efficacy of our intervention at evincing the aforementioned outcomes.

The dual nature of the data poses potentially challenging situations of consent, coercion, and confidentiality. We are sensitive to these issues and will adhere to the following procedures to mitigate these potential issues.

First, all professors will use this script to introduce the project to their students:

This semester I will be implementing an innovative series of simulations to help provide a more immersive educational experience than provided by traditional lectures. The Children's Advocacy Services of Greater Saint Louis at the University of Missouri – Saint Louis (UMSL) developed these learning materials through support from a grant from the Substance Abuse and Mental Health Services Administration. Part of this curriculum involves having you complete online pre- and post-measures. I will be using your participation in responding to these measures as part of your classroom grade. I will also use this information to improve my implementation of the simulations in future courses. However, because UMSL's grant is federally funded, they also need to evaluate the efficacy of their intervention. When you first sign on to the web site to complete the pre-intervention measure, you will see an informed consent form authorizing UMSL to retain your data for research purposes. It will be completely up to you as to whether or not you'd like to consent to being part of this research. Regardless of your decision to participate in the research, you will still need to complete these measures as part of this course. UMSL will transmit all response data to me. However, they won't tell me who did or did not consent for their data to be included in their research.

CASGSL has set up Qualtrics surveys to capture all data for this project. We will distribute corresponding URLs to instructors so that their students can complete pre- and post-intervention measures.

Because of the dual nature of our data, we will create two separate databases based on the responses we receive from the Qualtrics surveys:

- a) The first database will contain all students' responses to our measures. We will sort this database by classroom and create separate reports for each participating instructor. Using UM System's secure email service, we will send each instructor their classroom's data. The only data point that will not be in these data sets is whether or not a student consented to research.
- b) After creating the database described above, we will create a second database that will contain ONLY student data from individuals who had consented to participate in the research. All research analyses will be performed on this database.

The instructor will then integrate our intervention into their curriculum across the duration of the semester. Near the end of the semester, the instructor will complete ratings of their students on a number of dimensions (also via Qualtrics; see attached measures) and ask the students to return to our site to take a post-intervention assessment. We will follow the same procedures described above to ensure that we segregate data from consenting vs. non-consenting students.

Although this research project will last through the year 2021, we will ask for participants to renew their consent each year of the project. In order to ensure that we can follow-up with both our student and instructor participants over the duration of the project, our Qualtrics surveys will ask individuals to provide a permanent email address. Furthermore, to facilitate matching of responses in our database we will also ask participants to create a unique identification code that consists of their initials, birth month and date and their parents' first name initials.

EXPECTED DURATION.

In order to test our hypothesis about job retention, this research will last for a period of approximately four years and we will request approximately thirty minutes of participants' time every six months to complete the associated assessments. We will ask participants to provide email addresses so we can contact them biannually throughout the duration of our grant.

SAFETY PLAN FOR MANAGING RISK AND DATA COLLECTION PROCEDURES.

We will collect all of our data via the UMSL-approved Qualtrics surveying platform. Only CASGSL research staff will have access to the account associated with this data. Furthermore, and unlike other CASGSL projects, we will not allow any of our student research assistants access to this data. We will restrict student access to FORECAST data because we will be collecting professors' ratings of their students, and we do not want our RAs to have access to confidential data about any of their UMSL peers. We will download all Qualtrics data via UMSL's secure network and save research databases on CASGSL's secure server maintained by ITS. We will share student data with professors via encrypted email. UM System provides faculty access to a secure email service (<https://doit.missouri.edu/services/email/email-encryption/>). At the end of semester, we will reach out to each participating instructors using this secure email service and ask them to send us student ratings data. This will establish a secure link between us and the instructors and they will then be able to securely send data via attachments.

III. Risk/Benefit Assessment

Describe any RISKS TO THE SUBJECT that might arise from participation in the study. Subjects should be protected against injury and invasion of their privacy, and their dignity should be preserved. Risks fall under the following categories: physical, psychological, social, economic, legal, and other. Describe STEPS TAKEN TO MINIMIZE RISK. Describe the POSSIBLE BENEFITS TO THE SUBJECT. Describe the POSSIBLE BENEFITS TO SOCIETY.

There are no physical or economic risks from this study. Psychological and social risks include the triggering of uncomfortable affect when talking about trauma and trauma-related issues; however, these topic areas are routinely discussed in CAST courses regardless of FORECAST participation. Although there is some risk of data breach resulting in a loss of confidentiality, we will reduce the likelihood of this by restricting access to our Qualtrics surveys to only CASGSL research staff. Because all of these individuals have received training in the responsible conduct of human subjects' research, they are sensitive to the importance of maintaining data security.

Although participants may feel some discomfort in having their instructors rate their performance, this data will be instrumental in helping us judge the efficacy of our interventions. Furthermore, regardless of whether they participate in our research, students – by the very nature of being enrolled in a CAST course – will be evaluated by their instructor.

Additionally, we will conduct a lottery and randomly select five respondents to receive a \$20 gift card during each assessment session. The chances of winning a gift card will be dependent on the number of individuals who complete the

surveys. We anticipate having no more than 1500 student participants. We also anticipate having as many as 50 university instructors participate in this project – though they will not be eligible for any incentives.

IV. Debriefing Statement (if project involves deception)

Attach a copy of the debriefing statement explaining the deception. Deceptive techniques must be justified by the study's prospective scientific, educational, or applied value, and the investigator should explore equally effective alternative procedures that do not use deception. Investigators should not use deception when it would affect the subjects' willingness to participate (for example, deception regarding physical risks, discomfort, or unpleasant emotional experiences).

Not applicable. Project does not involve deception.

V. Participant Consent Form (s)

Attach all consent forms (on University or agency letterhead) and indicate how they will be maintained. The research investigator is responsible for retaining all signed consent documents for at least three years past the completion of the research activity.

See attached. This consent form will be displayed during the initial screens of our online assessment protocol described above.

VI. Assent Form (must be included if project involves minors)

Attach all assent forms (on University or agency letterhead) and indicate how they will be maintained. The research investigator is responsible for retaining all signed assent documents for at least three years past the completion of the research activity.

Not applicable. Only participants age 18 or over will participate in our study.

Applications for full committee review must be submitted on irbnet.org 10 days before the scheduled meeting in order to be reviewed that month. Please check the OAR web site (<http://www.umsl.edu/services/ora/IRB.html>) for a list of upcoming meeting dates.

Assessment Devices

Pre-assessment:

- *Demographic Questionnaire*
- *Core Concepts Questionnaire*
- *TIERS Questionnaire*
- *ARTIC*

Baker, C.N., Brown, S.M., Wilcox, P.D., Overstreet, S., & Arora, P. (2016). Development and psychometric evaluation of the Attitudes Related to Trauma-Informed Care (ARTIC) Scale. *School Mental Health, 8(1)*, 61-76.

Post-assessment:

- *Student Ratings of Simulation Activity*
- *Core Concepts Questionnaire*
- *TIERS Questionnaire*
- *ARTIC*
- *Instructor Ratings of Students*
- *Instructor Ratings of Simulation Activity*

Follow-up assessment:

- *Core Concepts Questionnaire*
- *TIERS Questionnaire*
- *ARTIC*
- *Instructor Ratings of Students*
- *Follow-up questions*