Office of Research Administration

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MODIFICATION REPORT

It is the policy of the UMSL IRB that all investigators submit a **Modification Report** if there are changes to an approved protocol. This form must be submitted through IRBNet. If this protocol is within 3 months of its annual review you may also simultaneously apply for **Annual/Continuation review**. Protocols can be renewed a maximum of four times. If this study has already been renewed four times and new subjects are to be recruited, the protocol must go through a new review.

Project Title:Foundations for Outreach Through Experiential Child Advocacy Studies Training (FORECAST)

Protocol Number: 1079048-2]

Principal Investigator: Joel Epstein **Department/College: CASGSL/Psych**

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1. **Modification to Study Protocol**
   ☒Yes ☐ No **Are you adding or deleting any measure(s)?**

   If Yes, explain the changes including any new risks or benefits,
   We are adding both post-simulation and follow-up assessments for student participants as well as instructor and supervisor ratings of students and trainees. In addition to the measures included in the pre-assessment, these new questionnaires include ratings of our simulation, an assessment of the fidelity with which the simulations were delivered, and a measure of job satisfaction/retention. Introduction of these items do not represent any new risks or benefits. The following list provides the names of the surveys we'll be deploying and the topics covered by each (all uploaded to IRBnet.org):

   FORECAST Student Initial (already received IRB approval)
   - consent
   - core concepts knowledge (cc)
   - trauma informed experiential and reasoning skills rating (tiers)
   - attitudes regarding trauma informed care (artic)
   - demographics

   FORECAST Student Post-Simulation Survey
   - contact and demographics
   - cc
   - tiers
   - artic
   - ratings of quality and fidelity of simulations (sim rating)

FORECAST Instructor
- consent
- info about courses taught/modules delivered
- sim rating
- ratings of student competencies
- demographics

FORECAST MDT Initial
- consent
- cc
- tiers
- artic
- demos

FORECAST MDT post-simulation
- contact and demographics
- cc
- tiers
- artic
- sim rating

FORECAST Student/Trainee Follow-up
- re-consent
- contact and demographics
- cc
- tiers
- artic
- job satisfaction
- job retention

FORECAST Supervisor
- consent
- ratings of student/trainee competencies
- employment info
- demographics

Include a copy of any new measure(s) along with this form.

☒ Yes ☐ No Is there a change in the recruitment of subjects (such as revised subject number, place of recruitment, recruitment ads)?

If Yes, explain the changes.
We are adding additional participating schools. Additionally, each participating school will also be recruiting individuals from their local multidisciplinary teams (MDTs) to participate in community trainings. These MDT participants will represent professionals (e.g., social workers, juvenile justice workers, police officers, case managers, etc.) who work within the community of our participating cohort partners. We will be training our partners to deliver our curriculum not only in their CAST courses, but also to community MDTs. We uploaded to IRBnet.org both the new consent forms for these indviduals, as well as recruitment scripts that will be used to explain the study.

Include a copy of any new advertisement(s) along with this form if needed.

2. **Changes in Personnel**
☐Yes ☒ No Will new personnel will be added to the protocol?

If yes, all new personnel will have to document IRB training. Describe role of new personnel

☐Yes ☒ No Will personnel will be leaving the protocol?

If yes, describe reason(s) why personnel are leaving

☐Yes ☒ No Will a new principal investigator will be added to the protocol?

If yes, describe new principal investigator

3. **Are there any other changes to the original protocol?** ☐Yes ☒ No

If yes, explain these changes.

4. **Do any of these modifications require a change to the consent form?**
☒Yes ☐ No

If yes, Include a revised consent with this form with changes highlighted.

If this protocol is within 3 months of its annual review you may also simultaneously apply for continuation review by completing the following questions.

1. **How many times has this protocol been renewed?**
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4

2. **Total number of subjects approved for this study:** 1,250
   Total number of subjects enrolled thus far in the study: 98
   Explain any discrepancies (such as the number of enrolled subjects exceeds the approved or if no subjects enrolled) in these numbers.
   five-year grant, just gearing up…

   If there is a discrepancy, are there changes in the potential risks (e.g. fewer subjects may impact confidentiality) or benefits (e.g., changes odds for drawings) that require a change in the consent?

3. **Have any serious or adverse events occurred in subjects since the last continuing review?** ☐ Yes ☒ No
   If yes explain.

4. **Has there been any additional or new information related to this study which may affect a subject's willingness to continue participation or that may need to be given to new subjects (such as complaints, unknown risks, recent literature)?**
   ☐Yes ☒No
   If yes, explain.