

**BRANY IRB LOCAL RESEARCH CONTEXT FORM**

**Protocol Title:** LearningClues LLC

(BRANY Study ID: 22-108-1250)

**Name of Lead Investigator (if applicable):** Perry Samson, Ph.D.

<b>Name of Institution/Organization:</b>	LearningClues LLC
<b>FWA number (if applicable):</b>	0990-0278
<b>Name of Local Investigator(s):</b>	Perry Samson
<b>Name and title of person completing this form:</b>	Perry Samson, Chief Technologist

1. What is the activity that will be conducted at this location?
  1. Survey to adult students in participating courses
  2. Focus groups with volunteering students in participating courses
  
2. Are there any local or requirements (including institutional/organizational policies), state laws or tribal law that stipulate requirements regarding the enrollment of a vulnerable population (e.g., children, pregnant woman, employees of the researcher, etc.) that will be included in this research?  
If yes, please provide details.  
**No**
  
3. Does local law or requirement (including institutional/organizational policies), state law, or tribal law stipulate requirements for the implementation and/or conduct of the protocol (examples: consent, age of majority, consenting process, GDPR) at your site that is different from what is described in the protocol?
  - No
  - Yes - Describe the relevant requirements and provide a link to any documents:
  
4. Are there any community, cultural norms with respect to research, individual autonomy, or religious differences of the local population, or ethical or religious directives of the institution/organization that have to be considered when reviewing this research for your site?
  - No
  - Yes – Explain:
  
5. Are there any investigations, audits, or findings (e.g., OHRP, FDA or local audits) over the past three years that would be relevant to the conduct of new human subject research proposed at the site?
  - No
  - Yes – Explain:

6. Is 18 the age of majority for the state in which the site is located?  
 Yes  
 No - Indicate age of majority:
7. What is the primary language(s) in the region(s) where the research will be conducted?  
 English  
 Other (specify):

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**Answer items 8-14 below if the research will be conducted outside of the U.S.**

**Check here to indicate that the research will not be conducted outside of the U.S.**

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8. Are the investigators who will be interacting with subjects fluent in the primary language of the subjects?  
 Yes  
 No – Explain who will facilitate the discussions with the subjects:
9. Describe the steps that will be taken to ensure that subjects and investigators are able to communicate with each other.
10. What are the investigator’s qualifications to conduct research in this setting?
11. Will the investigators be collaborating with local persons (e.g. – Researchers, Universities, Community Leaders, etc.)
12. Describe local collaborators (e.g. – Researchers, universities, Community Leaders, etc.)
13. Please provide a copy of the letter if support from the local collaborator.
14. Will this research be reviewed by a local IRB or ethics committee/review board?  
 No  
 Yes – Provide the following:  
a. A copy of the local IRB/ethics committee/review board approval letter  
b. Provide contact information for the IRB/ethics committee/review board representative.



Optional comments: None