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Date: September 29, 2025

PI: Arianna LaCroix

Re: Initial - IRB-2025-1005

Treating attention and language in post-stroke aphasia using a music-based intervention

The Purdue University Institutional Review Board has approved your study "*Treating attention and language in post-stroke aphasia using a music-based intervention*." The study administrative check in date is September 28, 2028.

The IRB must be notified when this study is closed. If a study closure request has not been initiated by this date, the Purdue HRPP/IRB will request study status update for the record.

Specific notes related to your study are found below.

Decision: Approved

Category:

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\)](#) and (b)(3). This listing refers only to research that is not exempt.)

Findings: N/A

Research Notes: N/A

Any modifications to the approved study must be submitted for review through [Cayuse IRB](#). All approval letters and study documents are located within the Study Details in [Cayuse IRB](#).

What are your responsibilities now, as you move forward with your research?

Document Retention: The PI is responsible for keeping all regulated documents, including IRB correspondence such as this letter, approved study documents, and signed consent forms for at least three (3) years following protocol closure for audit purposes. Documents regulated by HIPAA, such as Release Authorizations, must be maintained for six (6) years.

Site Permission: If your research is conducted at locations outside of Purdue University (such as schools, hospitals, or businesses), you must obtain written permission from all sites to recruit, consent, study, or observe

participants. Generally, such permission comes in the form of a letter from the school superintendent, director, or manager. You must maintain a copy of this permission with study records.

Training: All researchers collecting or analyzing data from this study must renew training in human subjects research via the CITI Program (www.citiprogram.org) every 4 years. New personnel must complete training and the PI must maintain records of their training certificates.

Key Personnel, those contributing in a substantive way to the scientific and scholarly development, execution, or interpretation of a project, must be added to the study protocol via modification in Cayuse. All other non-key personnel may begin working with human subjects and their data after they have completed CITI training requirements.

Modifications: Change to any aspect of this protocol or research personnel must be approved by the IRB before implementation, except when necessary to eliminate apparent immediate hazards to subjects or others. In such situations, the IRB should still be notified immediately.

Unanticipated Problems/Adverse Events: Unanticipated problems involving risks to subjects or others, serious adverse events, and noncompliance with the approved protocol must be reported to the IRB immediately through an incident report. When in doubt, consult with the HRPP/IRB.

Monitoring: The HRPP reminds researchers that this study is subject to monitoring at any time by Purdue's HRPP staff, Institutional Review Board, Post Approval Monitoring team, or authorized external entities. Timely cooperation with monitoring procedures is an expectation of IRB approval.

Change of Institutions: If the PI leaves Purdue, the study must be closed or the PI must be replaced on the study or transferred to a new IRB. Studies without a Purdue University PI will be closed.

Other Approvals: This Purdue IRB approval covers only regulations related to human subjects research protections (e.g. 45 CFR 46). This determination does not constitute approval from any other Purdue campus departments, research sites, or outside agencies. The Principal Investigator and all researchers are required to affirm that the research meets all applicable local/state/ federal laws and university policies that may apply.

If you have questions about this determination or your responsibilities when conducting human subjects research on this project or any other, please do not hesitate to contact Purdue's HRPP at irb@purdue.edu or 765-494-5942, or use our [online form](#) to request an appointment. We are here to help!

Sincerely,

Purdue University Human Research Protection Program/ Institutional Review Board
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