

**Institutional Review Board - Federalwide Assurance #00003152
University of Cincinnati**

Date: 11/6/2014

From: UC IRB

To: Principal Investigator: Elizabeth Harman
Child Life & Integrative Care

Study ID: [2014-0505](#)

Re: Study Title: Believe in Your Voice: A Music Therapy Intervention Program for At-Risk Youth

This study expires on: 7/14/2015.

An amendment to the above referenced protocol was reviewed and **APPROVED** using an **EXPEDITED** review procedure as set forth in 45 CFR 46.110(b) on **11/6/2014**.

We changed the layout of the consent form, to make it more readable.

We would like to expand the age range for participants from 15-17 to 14-18.

We would like to add Katelyn Reid to the study as an additional research assistant.

Revised Study Documents

Additional CITI Documents

CITI documents for Katelyn Reid (Groh)

COI Reid

Control Youth Assent Form

Intervention Youth Assent Form

Please note the following requirements:

Consent Requirements

Per 45 CFR 46.116 (21 CFR 50.20) the IRB has determined that informed consent must be obtained from all adult participants and that this consent must be documented by signature on the IRB approval consent form.

Parental Permission Requirements

There are no items to display

Assent Requirements

There are no items to display

HIPAA Requirements

There are no items to display

Language

There are no items to display

Language

There are no items to display

Language

There are no items to display

OTHER APPROVALS: Principal investigators are responsible for maintaining approval from other applicable review committees and performance sites. This includes, but is not limited to, Divisional Scientific Review committee, General Clinical Research Center (GCRC), Radiation Safety, Institutional Biosafety Committee (IBC), Conflict of Interest (COI) Committee, and any sites (i.e. schools, hospitals) where the research may be conducted. Principal investigators are also responsible for maintaining approval from the FDA and a valid contract between the sponsor and this institution, as applicable. If any of these entities require changes to the IRB-approved protocol and/or informed consent/assent document(s), the changes must be submitted to and approved by the IRB prior to implementation.

AMENDMENTS: The principal investigator is responsible for notifying the IRB of any changes in the protocol, participating investigators, procedures, recruitment, consent forms, FDA status, or conflicts of interest. Approval is based on the information as submitted. New procedures cannot be initiated until IRB approval has been given. If you wish to change any aspect of this study, please submit an Amendment via ePAS to the IRB, providing a justification for each requested change.

CONTINUING REVIEW: The investigator is responsible for submitting a Continuing Review via ePAS to the IRB at least 30 days prior to the expiration date listed above. Please note that study procedures may only continue into the next cycle if the IRB has reviewed and granted re-approval prior to the expiration date.

UNANTICIPATED PROBLEMS: The investigator is responsible for reporting **unanticipated problems** promptly to the IRB via ePAS according to current CCHMC reporting policy found on CenterLink.

STUDY COMPLETION: The investigator is responsible for notifying the IRB by submitting a Request to Close via ePAS when the research, including data analysis, has completed.

Statement regarding International conference on Harmonization and Good Clinical Practices:

The Institutional Review Board is duly constituted (fulfilling FDA requirements for diversity), has written procedures for initial and continuing review of clinical trials; prepares written minutes of convened meetings, and retains records pertaining to the review and approval process; all in compliance with requirements defined in 21 CFR Parts 50, 56 and 312 Code of Federal Regulations. This institution is in compliance with the ICH GCP as adopted by FDA/DHHS.

§46.110. Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

§46.108(b) An IRB may use the expedited review procedure to review either or both of the following:

1. some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
2. minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).