NATIONAL ENDOWMENT for the ARTS
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CREATIVE FORCES

MUSIC THERAPY OR ART THERAPY WITH MILITARY POPULATIONS
CLINICAL RESEARCH APPLICATION
RFA NUMBER: CF-2023-RCT-01

OVERVIEW: This required application is for a Randomized Controlled Trial (RCT)or large-scale prospective study. It includes a preliminary design for a subsequent RCT or other large-scale study. Please refer to ***Clinical Request for Applications: Music Therapy or Art Therapy with Military Populations, RFA Number CF-2023-RCT-01*** for full details. The RFA can be obtained at https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy or by contacting Enka Sodnom (esodnom@hjf.org).

LETTER OF INTENT TO SUBMIT: All applicants must submit a Letter of Intent (LOI) in advance of their proposal. The LOI must be submitted via email to Dr. Jay Uomoto (juomoto@hjf.org) and **received by May 16, 3:00 pm (EDT). The required LOI form is provided on** the Creative Forces National Resource Center (https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy). The LOI must include: Principal Investigator(s) with institutional affiliation, partners with institutional affiliation, the Creative Forces priority research question the study will address, and a brief abstract of the study.

RESEARCH PROPOSAL SUBMISSION: Applications (required application form and Section D attachments) **must be received by May 30, 3:00 pm (EDT).** Submit applications via PDF to Enka Sodnom (esodnom@hjf.org). ***NOTE***: Submission packages less than 10MB can be submitted via email. If larger than 10MB, please contact esodnom@hjf.org for a secure link to upload your proposal.

APPLICATION INSTRUCTIONS: This application form consists of:

- This **fillable PDF for sections A and D** which you will need to complete, save with a new name, and submit as a PDF.
- **Instructions for Sections B and C** which should be submitted as PDFs or Excel files as appropriate.

***Required forms and templates*:** Required forms and templates referenced in this application form and in the RFA can be downloaded at https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy.

***Electronic Signatures*:** Electronic signatures on PDF attachments within your application are allowed.

Formatting requirements for narrative section B:

Paper Size and Margins

- Use paper size no larger than *standard letter paper size (8 ½" x 11")*.
- Provide at least one-half inch margins (½") - top, bottom, left, and right - for all pages. No applicant-supplied information can appear in the margins.

Font (size, color, type density) and Line Spacing

Adherence to font size, type density, line spacing and text color requirements is necessary to ensure readability and fairness. Although font requirements apply to all attachments, they are

most important and most heavily scrutinized in attachments with page limits. Text in your attachments must follow these minimum requirements:

- **Font size**: Must be 11 points or larger. Smaller text in figures, graphs, diagrams and charts is acceptable, as long as it is legible when the page is viewed at 100%.
    - Some PDF conversion software reduces font size. It is important to confirm that the final PDF document complies with the font requirements.
- **Type density**: Must be no more than 15 characters per linear inch (including characters and spaces).
- **Line spacing**: Must be no more than six lines per vertical inch.
- **Text color**: No restriction. Though not required, black or other high-contrast text colors are recommended since they print well and are legible to the largest audience.

We recommended the following fonts, although other fonts (both serif and non-serif) are acceptable if they meet the above requirements.

- Arial
- Georgia
- Helvetica
- Palatino Linotype

Legibility is of paramount importance. Applications that include PDF attachments that do not conform to the minimum requirements listed above may be withdrawn from consideration.

Hyperlinks and URLs

- Hyperlinks and URLs are only allowed when specifically noted in the funding opportunity announcement (FOA) and form field instructions. The use of hyperlinks is typically limited to citing relevant publications in biosketches and publication lists. It is highly unusual for a FOA to allow links in Specific Aims, Research Strategy, and other page-limited attachments.
- Hyperlinks and URLs may not be used to provide information necessary to application review.
- **Reviewers are not obligated to view linked sites** and are cautioned that they should not directly access a website (unless the link to the site was specifically requested in application instructions) as it could compromise their anonymity.
- When allowed, you must hyperlink the actual URL text, so it appears on the page rather than hiding the URL behind a specific word or phrase.

Scanning

- Avoid scanning text documents to produce the required PDFs. It is best to produce documents using your word-processing software and then convert the documents to PDF. Scanning paper documents may hamper automated processing of your application for agency analysis and reporting.
- We recognize that sometimes scanning is necessary, especially when including letters of support or other signed documents on business letterhead.

Application Sections

A. **Description of Participating Entities** (complete as fillable PDF)
B. **Research Strategy**
C. **Budget**
D. **Attachments Checklist** (complete as fillable PDF)

A. DESCRIPTION OF PARTICIPATING ENTITIES

Definitions of entities:

Lead Principal Investigator (Lead PI) is the applicant and assumes overall responsibility for the research project and cross-site collaborations.

Site Principal Investigator (Site PI) is the principal investigator at the clinical site where subject recruitment occurs.

Clinical Partner is the institution/organization of the Site PI and the primary collaborator for the research project.

1. ***Lead Principal Investigator(s):***

Lead PI Name	
Title	
Address	
Phone Number	
Email	

2. ***Lead PI Institution/Organization (if dual appointments, include both):***

Name of Institution/Organization #1	
SAM CAGE Code	
Address	
Website	
Authorizing Official Name	
	(e.g., research director/administrator, individual who is legally authorized to act for the institution)
Title	
Phone Number	
Email	

Name of Institution/Organization #2	
SAM CAGE Code	
Address	
Website	
Authorizing Official Name	
	(e.g., research director/administrator, individual who is legally authorized to act for the institution)
Title	
Phone Number	
Email	

If applicable, please list the Research Staff personnel (include art therapists/interventionalists):

Name	Role (e.g., art therapist)	Institution/Organization

3. ***Clinical Partner and Site PI – Creative Forces Site or Non-Creative Forces Site:***

Clinical partner is a Creative Forces site:

- ○ Yes
- ◉ No

Clinical partner information

Institution/Organization	
Site PI Name	
Title	
Address	
Phone Number	
Email	

Clinical Partnership Description: Describe the roles and responsibilities and what the partner brings to the collaboration. Include information of the history of collaboration between partners, if any. If a non-Creative Forces site is designated, provide a justification for the choice of this partner. **Limit: 1200 characters**

4. ***Additional Partner (if applicable):*** Enter up to three

Partner 1

Institution/Organization	
Administrative Contact Name	
	(primary contact for the research partnership)
Title	
Address	
Phone Number	
Email	

Partner 1 Collaboration/Partnership Description: Describe the roles and responsibilities and what each partner brings to the collaboration. Include information of the history of collaboration between partners, if any. **Limit: 1200 characters**

Partner 2

Institution/Organization	
Administrative Contact Name	
	(primary contact for the research partnership)
Title	
Address	
Phone Number	
Email	

Partner 2 Collaboration/Partnership Description: Describe the roles and responsibilities and what each partner brings to the collaboration. Include information of the history of collaboration between partners, if any. **Limit: 1200 characters**

Partner 3

Institution/Organization	
Administrative Contact Name	
	(primary contact for the research partnership)
Title	
Address	
Phone Number	
Email	

Partner 3 Collaboration/Partnership Description: Describe the roles and responsibilities and what each partner brings to the collaboration. Include information of the history of collaboration between partners, if any**. Limit: 1200 characters**

5. ***Biosketches:*** Submit a biosketch for each member of the research team (Principal Investigator(s) and all collaborators/partners , co-investigators, supervisors) central to creation of the proposal. Use the format provided in the biosketch template; maximum of 5 pages per individual. Compile all biosketches into one PDF and submit as an attachment (see Section D). The biosketch template can be downloaded at https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy.

6. ***Letter(s) of Collaboration for all partners listed in A.3 and A.4:*** Letters should be addressed to the Lead PI, be submitted on the partner's letterhead, and indicate full endorsement and support for the project. Combine letters of collaboration into a single PDF and submit as an attachment (see Section D).

   - The letter from the **Clinical Partner (A.3)** should be signed by the **Site PI** (e.g., clinical supervisor, facility director, chief of research) according to local policy. For **partnerships with Creative Forces**, the letter should be signed by the Creative Forces site director and the creative art therapist(s) providing services for the study.
   - Letters from **Additional Partners (A.4)** should be signed by the contact named in that section.

7. ***Letter of Institutional Support:*** Submit a letter from the Lead PI's institution demonstrating institutional support for and commitment to the research project and summarizing the agreements and resources they have, or will have, in place to support the study.

NOTE: At a minimum, letters of support/collaboration/agreement should stipulate expectations for level of effort, responsibilities, co-authorship, access to core facilities/resources, and fees-for-service *as appropriate to the relationship.* **Institutional Review Board approvals and data-sharing agreements are not expected at the time of application but should be addressed in the study timeline and implementation plans.**

B. RESEARCH STRATEGY

Submit Section B. *Research Strategy* as a single, separate PDF (see Section D) with the study title (B.1), abstract (B.2), and detailed description (B.3 – B.7). Sections B3 – B7 should not exceed 6 pages, excluding timetable (B.5.l). Submit timetable as an attachment (see Section D).

Identify each item below by number and letter in your description.

1. ***Title***: Study title.

2. ***Abstract***: Briefly describe the RCT or large-scale prospective study. [500 words]

3. ***Background and Significance***: Briefly sketch the background for your research question. Critically evaluate existing knowledge (published literature, clinical trials, etc.) and identify specific gaps the project intends to fill. How will this research advance scientific knowledge and/or clinical practice? Describe the effect of this research on the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field. Describe any new methodology and its advantage over existing methodologies, and/or novel concepts, approaches, tools, or technologies. Explain how the proposed study helps to answer the selected Creative Forces priority research question in music or art therapy.

4. ***Question/Hypotheses***: Identify the research question(s) and hypothesis for the RCT or large-scale prospective study.

5. ***Research Design and Methods for Feasibility/Pilot Study:*** This section should provide a clear understanding of the research design, procedures, and analyses. A power analysis should be included.

   Describe the research design and methodology, **identifying each item below by letter** in your description.

   a. **Research Design**: Description of the research design, including how the specific aims are best addressed with the proposed research design. Include an explanation of how the results of the RCT or large-scale prospective study can potentially inform the impacts of music or art therapy in common clinical practice.
   b. **Study Population**: Describe the study population from which recruitment is aimed. State the number of participants and include a power analysis to justify this number. Based upon prior experience or other similar studies, estimate the attrition rate and include the number needed to enroll to achieve the desired number of participants.
   c. **Intervention**: Description of intervention including activity; number, length, and frequency of sessions; and the length of a follow-up period, if applicable. Include procedures for monitoring and reporting treatment fidelity.
   d. **Location**: Location of study/intervention activities.

e. **Participant Recruitment**: Describe participant recruitment strategies, including control groups if applicable. Include additional or alternative recruitment strategies should planned recruitment fall short of expected benchmarks.
f. **Participant Selection**: Describe participant selection, including data describing the inclusion/ exclusion criteria at the recruiting site(s) and number(s) of potential participants available. The proposal should provide evidence of the feasibility of recruiting the sample, based on recruitment timeline, the number of participants needed to reasonably evaluate study objectives, and potential budget restrictions.
g. **Measures**: Describe and justify measures used in the study.
h. **Data Collection Methodology**: Describe data collection tools and methods and their appropriateness to the research design. .
i. **Data Analysis Plan**: Describe the statistical approach and interpretation that will be used to answer the questions under investigation.
j. **Data Management Plan**: Describe plans for data access, sharing, protection/privacy, and archiving.
k. **Interpretation**: Describe potential results and interpretations.
l. **Timetable**: Provide a timetable for the project (preparation for the study, IRB, recruitment, intervention, data analysis). Use a Gantt Chart or other similar format. **Submit as an attachment; see Section D**.
m. **Limitations and Alternative Approaches**: Describe potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the study's aims.
n. **Dissemination Plan:** Describe the plan to disseminate the results from this research, such as publishing briefs, presenting findings at a national conference, publishing in an academic journal, etc., and the target audience.

6. ***Research Facilities/Resources/Equipment*:** Describe facilities and other physical resources for the research.

7. ***Risk Assessment*:** Identify any procedures, situations, or materials that may be hazardous to participants and the precautions to be exercised, and activities and strategies to minimize risk.

C. BUDGET

Budget: The RCT or large-scale prospective study will be incrementally funded over the subaward period of 32 to 34 months. The total budget cannot exceed a total of $900,000, including indirect costs.
Funding is to be provided in the following increments:

Phase 1: August 2023-May 2024 - $200,000
Phase 2: June 2024-May 2025 - $350,000
Phase 3: June 2025-April 2026 - $350,000

No additional funds are available to pay for institutional indirect costs. No cost sharing or matching is required. Note that Creative Forces clinicians' salaries and benefits are already covered by pre-existing employment arrangements by Creative Forces/Henry M. Jackson Foundation for the Advancement of Military Medicine. This subaward cannot be used to pay federal salaries.

Provide an itemized budget and budget justification for the RCT or large-scale prospective study using the detailed guidelines and templates, available at https://www.creativeforcesnrc.arts.gov/news/research-funding-available-art-therapy-and-music-therapy or by contacting Enka Sodnom (esodnom@hjf.org). **Submit as attachments; see Section D.**

D. ATTACHMENT CHECKLIST

The following attachments should be submitted via email, along with this completed application form. Check each box to indicate the included attachments.

- ☐ ***Section B Research Strategy:*** Submit as one PDF.
- ☐ ***Study Timetable:*** Submit as one PDF; see Section B.5.l.
- ☐ ***Itemized Budget and Justifications forms:*** See Section C.
- ☐ ***Biosketches:*** Combine and submit as one PDF; see Section A.5.
- ☐ ***Letter(s) of Collaboration:*** Combine and submit as one PDF; see Section A.6.
- ☐ ***Letter of Institutional Support***: Submit as one PDF; see Section A.7.
- ☐ ***Additional Letters of Support (optional)***: Attach any additional letters necessary to demonstrate the support of key contributors, senior personnel, and/or collaborators. Combine and submit as one PDF.