Award Number: W81XWH-12-1-0031

TITLE: Research in Prevention and Treatment of Noise-Induced Hearing Loss (NIHL)

PRINCIPAL INVESTIGATOR: Dr. Kathleen Campbell

CONTRACTING ORGANIZATION: Board of Trustees of Southern Illinois University Springfield, IL 62702-4910

REPORT DATE: April 2013

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

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**4. TITLE AND SUBTITLE**
Research in Prevention and Treatment of Noise-Induced Hearing Loss (NIHL)

**6. AUTHOR(S)**
Dr. Kathleen Campbell

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
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Springfield, IL 62702-4910

**9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)**
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland  21702-5012

**11. SPONSOR/MONITOR’S REPORT NUMBER(S)**

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**14. ABSTRACT**
Tasks include ABR data collection, solution preparation, animal injection, animal noise exposure, histological microdissection, ABR analysis, SEM analysis, and animal protocol development. ABR threshold analysis is conducted daily. Microdissection and SEM work are conducted daily. SEM analysis is conducted as samples are prepared. Preliminary outer hair cell analyses support statistically significant otoprotection for impulse and steady state noise-exposed animals that were observed by ABR analysis.

**15. SUBJECT TERMS**
none provided

**16. SECURITY CLASSIFICATION OF:**
a. REPORT U  b. ABSTRACT U  c. THIS PAGE U  19a. NAME OF RESPONSIBLE PERSON USAMRMC

**17. LIMITATION OF ABSTRACT**
UU

**18. NUMBER OF PAGES**

**19b. TELEPHONE NUMBER (include area code)**
1. Project Status

a. Outcome Summary and Issues

Write salient bullet points to highlight the following requested information.

ACCOMPLISHMENTS:
This may include completion of milestones, objective, and/or tasks, regulatory approval received, publication of paper, presentation at conference, filing of intellectual property, etc. Include quarter period accomplished, followed by date in DD-MMM-YYYY.

1. Experimentation complete for 50/50 year 1 impulse animals. 3-Aug-2012.
2. Experimentation complete for 50/50 year 1 steady state animals 16-Nov-2012.
3. Cochlear dissection, SEM prep is complete for all impulse animals. Impulse animal SEM analysis is near completion 12-Apr-2013.
4. Year 2 animal protocols approved by SIU Laboratory Animal Care and Use Committee and ACURO. 18-Jan-2013.
5. Cochlear dissection and SEM prep is currently in progress for steady state animals. Steady state SEM analysis is in progress.
6. Impulse and steady state animal SEM outer hair cell analysis is currently in progress.

PRODUCTS:
This may include development of a prototype, a new methodology, or any other similar item considered as a deliverable.

1. ABR analysis has determined an optimal dose range for D-met otoprotection for impulse and steady state animals. Preliminary outer hair cell analyses confirm ABR data.
2. Lab staff continues cytocochleogram whole mount training.

ISSUES:
List current problems that may impede performance or progress of this project. This may include administrative, technical, and/or logistical issues. Include actions taken to correct or overcome it.

- Expenditures were less than projected because histological analyses are not yet completed and billed. Further, 7 of the Year 1 animals required postponement due to excessive construction noise in our animal care facilities, scheduled to end mid-May 2013.

b. Progress Summary

Please include a brief summary concerning the status of your project. Address technical progress aligned with schedule, but exclude discussion of costs in this section. Add additional row for each quarter to create a table showing all quarters to date.

| Quarter 1: | Animal protocol approval and equipment setup are complete. 30/50 animals have been exposed to impulse noise and near completion of their injection schedule. Experimental schedule |
is planned to complete impulse and steady state animal groups by the end of the year. Data collection for the year is approximately 20% complete. Data collection will progress more quickly now that noise exposure system and animal approvals are in place for the entire year.

Quarter 2: Data collection continues. All year 1 impulse-tested animals have completed experimentation. 15/50 year 1 steady-state-tested animals have completed experimentation. The majority of steady-state animals are scheduled to complete experimentation by the end of this quarter. Histological outer hair cell analysis for all animals continues to progress.

Quarter 3: Animal experimentation is complete for 100/100 Year 1 animals. Histological data collection is currently in progress.

Quarter 4: Impulse animal cochlear dissection and scanning electron microscopy (SEM) preparation are complete. Steady state animal cochlear dissection and SEM preparation are underway. We have institutional and ACURO approval for Year 2 animal protocols and are currently scheduling Year 2 animal experimentation.

c. Progress Detail
Describe each task or logical segment on which effort was expended during this quarterly reporting period only, including pertinent data and graphs in sufficient detail to explain any significant results achieved. Methodology used should be succinct.

Tasks include ABR data collection, solution preparation, animal injection, animal noise exposure, histological microdissection, ABR analysis, SEM analysis, and animal protocol development. ABR threshold analysis is conducted daily. Microdissection and SEM work are conducted daily. SEM analysis is conducted as samples are prepared. Preliminary outer hair cell analyses support statistically significant otoprotection for impulse and steady state noise-exposed animals that were observed by ABR analysis.

2. Budget Status
Provide financial information requested below. Add additional row for subaward greater than one and include the name of the organization receiving the subaward.

<table>
<thead>
<tr>
<th></th>
<th>Quarter 1</th>
<th>Quarter 2</th>
<th>Quarter 3</th>
<th>Quarter 4</th>
<th>Cumulative</th>
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<td>Other Subaward</td>
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3. Protocol Status

**Human Use Regulatory Protocols**

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<th>Protocol Title</th>
<th>Required for Clinical Significance</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>10 animals per group</td>
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</tbody>
</table>

**Animal Use Regulatory Protocols**

<table>
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<tr>
<th>Protocol Title</th>
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<tbody>
<tr>
<td>D-methionine Dose Response Curves for Prevention of Noise Induced Hearing Loss (NIHL) for Steady State and Impulse Noise</td>
<td>10 animals per group</td>
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</tbody>
</table>

**Submitted to and Approved by:**

- LACUC – 11-Oct-2011: Protocol # 93-11-017
- ACURO – 19-Oct-2011

**Status:**

- Protocol is active.
- 1 amendment was submitted to change anesthesia to reduce animal mortality. The new anesthesia has resolved the problem.
- 6 amendments were submitted to add personnel to the protocol