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### OFFICE FOR THE PROTECTION OF HUMAN SUBJECTS

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FWA#00006252

August 14, 2008

David Wessel (wessel@cnmat.berkeley.edu) Psychology CNMAT 1750 Arch Berkeley, CA 94720

## **RE: CPHS Protocol #2008-7-30**

"The Design of Digital Hearing Aids that Provide Satisfying Music Listening Experience" - Faculty Research - UC Discovery and Starkey Hearing - Psychology

# Dear Professor Wessel:

Thank you for submitting an application for approval of the above-referenced protocol. Your submission has been reviewed and approved on an expedited basis, under Category F(7) of the federal regulations, for one year or less, effective 8/13/2008. This approval will expire on 8/12/2009.

The number of this approval is **2008-7-30.** Please refer to this number in all future correspondence.

## Please note the following:

1. The attached stamped, approved consent materials must be used for the consenting of any new subjects.

Continuation/Renewal: Approximately 8 weeks before the expiration of this approval, OPHS will send you a courtesy reminder. Applications for continuation review should be submitted no later than 6 weeks prior to the expiration date of the current approval to allow sufficient time for the renewal process. Note: It is the responsibility of the Lead Investigator to submit for renewed approval in a timely manner. In keeping with federal regulations, if approval expires, all research activity (including data analysis) must cease until re-approval from CPHS has been received. Before applying, please check current CPHS guidelines, instructions and forms available at http://cphs.berkeley.edu.

Amendments/Modifications: Any change in the design, conduct, or key personnel of this research must be approved by the CPHS *prior* to implementation. (For more information, see "<u>Process for Submission & Review of Applications</u>" and "<u>Application Forms & Informed Consent</u>" on CPHS website).

Unanticipated Problems and Adverse Events: If any study subject experiences an unanticipated problem involving risks to subjects or others, and/or a serious adverse event, the CPHS must be informed promptly within no more than one week (7 calendar days), and receive a written report within no more than two weeks (14 calendar days), of recognition/ notification of the event. (For more information on definitions and reporting requirements related to this topic, see "Adverse Event and Unanticipated Problem Reporting" on the CPHS website).

If you have any questions about the above, please contact the Office for the Protection of Human Subjects staff at (510) 642-7461; Fax (510) 643-6272; or e-mail <a href="mailto:ophs@berkeley.edu">ophs@berkeley.edu</a>.

Thank you for your cooperation and your commitment to the protection of human subjects in research.

Sincerely,

Jane Gilbert Mauldon, Ph.D

Acting Chair, Committee for Protection of Human Subjects Associate Professor, Goldman School of Public Policy

Jane Silbert Moulden

JGM: mj

Cc: Anne-Marie Bonnel (ambonnel@berkeley.edu)