

6500 (Human Volunteers)

Pers-A212a-11a

~~SECRET~~

SECOND ENDORSEMENT on CO NH San Diego ltr 1/3-kh 6500 ser 1466 of
10 Dec 1963

From: Chief of Naval Personnel
To: Secretary of the Navy

Subj: Permission to enter research project with San Diego Hearing
Society; request for

1. Forwarded.

2. Since the Chief, Bureau of Medicine and Surgery has indicated that
the normal functions of the U. S. Naval Hospital, San Diego would not
suffer, the Chief of Naval Personnel has no objection to approval of this
request.

~~SECRET~~

BURDICK H. BRITIN
BY DIRECTION

Copy to:
CO NH San Diego
BUMED-713

JAN 27 1964
Approved _____ 19
Paul B. Fay, Jr.
PAUL B. FAY, Jr.
Under Secretary of the Navy

RETURNED TO ORIGINATOR FOR
DISPOSITION THIS DATE 28 JAN 1964
GAP

DISPATCH SYMBOL
355

NAV1.941006.079

A 21

Adc -

BUMED-713:O'D:esk
8 Jan 1964

FIRST ENDORSEMENT on CO NH San Diego ltr 1/3-kh 6500 ser 1466
of 10 Dec 1963

From: Chief, Bureau of Medicine and Surgery
To: The Secretary of the Navy
Via: Chief of Naval Personnel

Subj: Permission to enter research project with San Diego Hearing
Society; request for

1. Readdressed and forwarded, recommending approval.
2. It is considered that there would be very little demand on the
time of hospital personnel in carrying out this research project,
so that the normal functions of the hospital (care of service
personnel and dependent personnel) would not suffer.



A. S. CHRISMAN
Deputy and Assistant Chief

Copy to:
CO NH San Diego

**U. S. NAVAL HOSPITAL
SAN DIEGO 34. CALIFORNIA**

IN REPLY REFER TO:

1/3-kh
6500
Serial: 1466
10 December 1963

From: Commanding Officer, U. S. Naval Hospital, San Diego, California 92134
To: Chief of Naval Personnel
Via: Chief, Bureau of Medicine and Surgery

Subj: Permission to enter research project with San Diego Hearing Society; request for

Ref: (a) Art. 1-7 through 1-11, MMD

Encl: (1) Copy of request for participation from San Diego Hearing Society

1. This hospital has been requested to assist the San Diego Hearing Society with a proposed infant testing program as set forth in enclosure (1).

2. A conference was held at which the Chief, Otolaryngology Service, the Chief, Pediatrics Service of the Naval Hospital, San Diego, together with medical officers of their respective services, met with representatives of the San Diego Hearing Society. It was concluded that this project was both desirable and feasible.

3. It was agreed that, upon approval, the research would be undertaken under the conditions as outlined below:

a. Test personnel and equipment will be furnished by San Diego Hearing Society.

b. Test personnel are not to touch or handle the infants under test. All such handling is to be accomplished by nursery personnel.

c. Test equipment is to be left in the designated test space so as to minimize environmental cross-contaminations.

d. Testing personnel are not to appear to conduct testing if experiencing any infections, particularly the use of oro-dental, cutaneous, or gastrointestinal types.

e. Test personnel are to enter by a designated entry, to don protective cap, mask and gown at a designated place, and to enter the designated testing space directly. They are to remain thereafter in the designated testing space and are to have no access to other nursery spaces.

f. The Naval Hospital will furnish personnel, as available, as follows:

(1) One pediatric resident to attend to general physical examination and general health of the infant, and to insure conformance with nursery regulations and the protective provisions of this agreement.

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(2) One E.N.T. resident to examine the infant otologically and insure his anatomic and physiologic aural integrity prior to actual testing.

(3) Nursery personnel will deliver the infant to the test area, remove it from the test area, and monitor the infant for safety from contaminating maneuvers during the presence of the infant in the testing area.

g. Space. A space acoustically and environmentally secluded from the remainder of the nursery is available and will be assigned for this research by the Chief of Pediatrics.

h. Scope. At present, a pilot study on 100 infants is planned to establish the response norm for the planned test stimulus (recorded baby's cry) and establish the approximate average sound pressure level which a response threshold occurs. If the pilot study demonstrates that the method has consistent qualitative value in auditory testing in newborns, authorization for additional tests may be requested in an effort to quantitate the test procedure.

i. Method. The tone stimulus for hearing testing will be a tape recording of an infant's crying presented through a portable tape recorder with small attached "goose neck" loud speaker aimable to present the test tone to both ears, or to favor either ear, without actual contact. The output of the speaker at the test distance will be pre-calibrated. Test crying tone will not be presented at sound pressure levels sufficient to cause acoustic fatigue or trauma.

(1) It is intended to test about five infants at each test period.

(2) It is intended to test each infant $\frac{1}{2}$ to 1 hour before feeding when quiet, comfortable, and awake.

(3) Permission from the parents will be obtained in each instance prior to testing.

(4) Records will be kept on a cross-keyed, date and initial basis, with no names in test or published reports. In event of suspected hearing loss in an individual infant, he can be back-traced by the date-initial coding so that his parents can be advised of apparent need for additional testing and possible treatment.

(5) In the event of publication of results, the Naval Service and the U. S. Naval Hospital, San Diego will be credited for participation in the study.

4. The project will be subject to termination by the Commanding Officer, U. S. Naval Hospital, San Diego, California, without prior notice, if he

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deems termination to be in the best interest of the personnel involved or of the Naval Service.

5. In view of the information that may be obtained from these tests in addition to the community service which may be rendered, it is requested that this request be considered in accordance with reference (a).


H. J. COKELY

MEMBER



AGENCY

San Diego Hearing Society

3843 HERBERT STREET—PHONE 298-4161
SAN DIEGO 3, CALIFORNIA

A COMMUNITY



CHEST AGENCY

MEMBER OF COMMUNITY WELFARE COUNCIL

October 23, 1963

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EXECUTIVE DIRECTOR
DONALD F. KNESS

Commanding Officer
U.S. Naval Hospital
San Diego, California 92134

Dear Sir:

We are writing this letter to explain a proposed "infant testing program" and to enlist your active participation in the study.

Various tests to evaluate the hearing of infants have been proposed and pursued for several years. Testing of infants' hearing is gross and the parameters are broad. The gross tests that are employed at the present time involve the use of various noise makers to elicit a startle reflex in the infant. Problems that have been encountered with these tests are numerous, including the fact that most infants do not respond at threshold levels. Indeed, response may not be achieved until well above organic threshold.

Generally no psychological interplay takes place with these tests. Only reflex actions are observed.

Objectives

It has been the observation of the professional staff of the San Diego Hearing Society that infants will respond to a tape recorded infant's cry at levels much lower than those necessary for tonal or noise presentation.

It may be hypothesized that an infant attaches little meaning to tone or noise which he cannot identify. Conversely, a recorded infant cry may cause him to respond in like manner because of the meaningful stimulus. Some support to this hypothesis has been the observation that this "cry response" occurs between 40 and 50db above threshold. This level of response has been a more consistent level than response to other stimuli. This then is what we wish to investigate; is this response to recorded cry greater than chance when compared with response to other methods of stimulus presentation?

ENCLOSURE (1)

Objectives: To Prevent Deafness — Conserve Hearing — Rehabilitate the Hearing Handicapped

Many factors enter into the proposed procedure. First, it must be ascertained whether the child's physical and emotional environment will permit the operator to achieve valid measures of auditory response. Therefore, the need for a large test population is indicated due to the variables involved. The patient load of infants at the San Diego Hearing Society is so small that it would take a considerable period of time to obtain sufficient data necessary to establish validity of the test. It is with this in mind that we are asking the Naval Hospital's assistance in gathering this data.

Procedures

The infant under test should first be evaluated by a pediatrician and an otologist and a statement made as to the physical state of the infant at that time. Their evaluation should include any possible outer or middle ear pathology and any other physical abnormality which might have bearing on the outcome of the test.

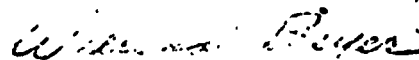
During the audiological testing it will be necessary to place the infant in a quiet environment away from the influence of other infants. The audiological procedure will be primarily a test involving controlled levels of presentation of test stimuli which in this case will be a recording of an infant crying. The stimuli will be presented at pre-determined sound pressure levels to elicit the response. All equipment and personnel required for audiological testing will be furnished by the San Diego Hearing Society.

Credit will be given to the Naval Hospital in any publication relating to this study.

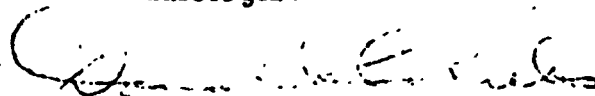
The director of the San Diego Hearing Society, who will be responsible for this study, is presently consultant and lecturer in audiology to the ENT Clinic of Naval Hospital.

We will greatly appreciate any assistance you may give us concerning the pursuit of this proposed study.

Sincerely,



Willena Beyer
Audiologist



Donald F. Krebs, M.A.
Executive Director

WB/wh