UACCESS EDOC NUMBER (FOR PROJECTS REQUIRING AN IRB FEE)

PROJECT TITLE: Neurology of Musical Grammaticality in Trained Musicians

INVESTIGATOR

Principal Investigator Name, Degree(s): Thomas G. Bever

Principal Investigator UA netID [redacted]

Status/Rank: Regents' Professor

Center:

Section:

Department: Linguistics

College: Social & Behavioral Sciences

Contact phone: 520-626-6366

Official University Email: tgb@email.arizona.edu

ADVISOR CONTACT INFORMATION (REQUIRED FOR ALL STUDENTS AND RESIDENTS)

Name, Degree(s), UA NetID:

Contact phone:

Official University Email:

ALTERNATE/COORDINATOR CONTACT INFORMATION

Name, UA NetID: [redacted]

Contact phone: [redacted]

Official University Email: [redacted]

SECTION 1: REQUIRED SIGNATURES

1. PRINCIPAL INVESTIGATOR

I will conduct my research according to the University of Arizona HSPP Investigator Manual.

[redacted] 3/27/2014 Thomas G. Bever

Signature | Date | Print Name

2. ADVISOR (FOR ALL STUDENTS AND RESIDENTS ACTING AS THE PI)

I will oversee the student researcher according to the University of Arizona HSPP Investigator Manual.

Signature | Date | Department

3. SCIENTIFIC/SCHOLARLY REVIEW (CANNOT BE ASSOCIATED WITH THE PROJECT)

I have examined the proposal cited above, and find that the information contained therein is complete and that the scientific or scholarly validity of the project appears appropriate.

[redacted] 27 March, 2014 Adam Ussishkin

Signature | Date | Print Name

ussishki@email.arizona.edu | 626-7121

Official University Email | Phone number

4. DEPARTMENT/CENTER/SECTION REVIEW

I have reviewed this application and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research.

[redacted] 3/31/14 Ofelia Zepeda

Signature | Date | Print Name

ofelia@email.arizona.edu | 621-8294

Official University Email | Phone number

SECTION 2: GENERAL INFORMATION

1. Not including this project submission, how many:

a. Human Research studies is the PI involved in as key personnel? 1

b. Active subjects are there in the PI's open Human Research study/ies? 150

c. Investigators are involved on the PI's open Human Research studies? 2

d. Research coordinators are involved on the PI's open Human Research studies? 0

2. What is the expected length of this project? up to 5 years

3. Retention of study materials before, during, and after completion of the project:

a. Where will the original signed consent and PHI Authorization documents be stored (building name and room)? n/a

b. How long will the data/consents be kept after conclusion of the project?
- ☐ 6 years
- ☒ Other: indefinitely

4. If the Human Research project is funded, identify all sponsoring entity/ies): n/a

5. If funding support is from a federal agency (such as a training grant, infrastructure grant, salary support, project grant, etc.), list federal agency and grant number n/a

6. Total funding amount **OR** per subject amount: n/a

7. The Principal Investigator hereby affirms that ALL individuals who meet the definition of "investigator" for this project in the current "Policy on Investigator Conflict of Interest in Research" have completed the mandatory Conflict of Interest training (http://orcr.arizona.edu/coi/training) and Disclosure of Significant Financial Interests (https://uavpr.arizona.edu/COI/). ☒ Yes

8. Will this project be registered on ClinicalTrials.gov because …? ☐ Yes ☒ No

a. the local PI is the sponsor of the clinical trial (including NIH-funded clinical trials where the local PI is the funding recipient OR IND holder);
OR

b. The PI has been designated by a sponsor, contractor, grantee, or awardee to register the clinical trial to ClinicalTrials.gov, as the Responsible Party (responsible for conducting the trial, and has sufficient data rights)

If yes, please check the appropriate box:
- ☐ ClincialTrials.gov "NCT" number for this trial (define):
- ☐ Registration pending

☐ Clinical trial does not require registration (click above to see what studies qualify)

SECTION 3. PROJECT NARRATIVE

1) Background

Previous research has identified behavioral differences between right-handed individuals with a left-handed family member (familially sinistral, FS+) and those with only right-handed family members (FS-) on psycholinguistic tasks. Additionally, FS+ individuals show more bilateral neural activity relative to the traditionally lateralized activity seen in FS- during syntactic processing, particularly in the frontal lobe and basal ganglia. Evidence that music and language processing recruit overlapping brain regions suggests that differences between FS+ and FS- individuals may be apparent in music tasks as well as language, and a previous study found a significant difference between FS+ and FS- individuals that corresponded to the degree to which they were genetically predisposed to left-handedness.

2) Lay Summary (approximately 400 words)

The proposed project will complement our behavioral studies of familial handedness effects with electroencephalographic (EEG) measures of neural activity while listening to coherent and incoherent chords. Subjects will be screened for familial handedness and psychological conditions listen to chord sequences while their brainwaves are monitored through an electrode net. Subjects will additionally be chosen on the basis of having had musical training sufficient to recognize "grammatical" chord sequences. This study will increase our understanding of how a family history of left-handedness, a presumed marker for genetic and neural differences, may influence neural architecture, particularly with regard to neural timing and synchrony. The current study's focus on trained musicians means that more subtle senses of "grammaticality" in sequences can be explored, as well as the effect of expertise on brain responses to ungrammatical musical chord sequences.

3) Setting of the Human Research

This research will be conducted in Thomas Bever's Language and Cognition Lab, rooms 304, 306, and 308 in the Communication Building. Participants will be briefed before and after their participation in these same rooms.

4) Resources available to conduct the Human Research

High quality audio playback equipment will be used to maximize the perceptual effects under study. The laboratory in which the experiment will take place contains an electroencephalogram (EEG) machine connected to an Apple computer to record EEG output, with a PC computer to run the behavioral experimental software by which the stimuli will be presented to the participants and by which the participants will overtly respond. This equipment is dedicated to use by the Bever Lab, and access will be effectively unlimited.

Thomas Bever has experience designing and conducting dichotic listening experiments as well as numerous other behavioral and EEG experiments. Research assistant Dane Bell has undergone practical training in EEG measurement and analysis from the manufacturer of the equipment to be used in the human research. On the basis of this expertise, all other personnel will be trained to ensure safety, accuracy, and consistency in measurement. This training will include modeling correct application of EEG nets, use of the collection and presentation software, and participant rights, as well as regular evaluation and review.

5) Study Population

Participants will be recruited from the University of Arizona Department of Psychology Research Subject Pool or from the local community on a volunteer basis. Eligibility criteria include:

- ages 18-35
- no history of traumatic brain injury or organic neurological impairment per self-report
- no open head wounds at the time of participation
- no hairstyles that would prevent good electrode contact, such as dreadlocks and tight braids
- no subjects whose hair is dyed with certain red dyes known to stain electrode nets
- minimum 5 years' experience playing at least one musical instrument
- no known hearing impairment

An effort will be made to recruit equal numbers of male and female participants and with and without familial sinistrality. No preference will be made on the ethnicity or race of potential subjects, so the racial background will reflect that of available subjects. Although some subjects may incidentally be pregnant women, they would be at no greater risk than other subjects.

6) Recruitment Methods and Consenting Process

Participants will be recruited from Psychology courses via a website hosted by the Department of Psychology, or via direct emails from study personnel to subjects meeting handedness criteria. Students will participate in experiments for partial course credit. Alternatively, students have the option of writing a paper for equivalent credit. The web recruitment information (Attachment 3) will be provided on the website. All subject pool members will be able to view the descriptions in Attachment 3 and self-identify by emailing the PI to request the study password. Interested students will then be contacted using the prescreening templates (Attachment 3). Participants meeting inclusion criteria will then be sent a second email (Attachment 3) with a study password allowing them to sign up for the study.

Since the desired study population of musicians may be difficult to identify and attract from the student subject pool, eligible subjects will also be drawn from the general population on a volunteer basis. Recruitment in these cases will be informal and carried out by word of mouth on the notion that musicians will know other musicians.

This recruitment process will also provide enough time for potential subjects to consider whether to participate, and because of the minimal-risk nature of the experiment, this is expected to provide enough time to consider participation.

Up to 60 subjects will be recruited in the course of the whole study.

Subjects will be informed of the study aims and methods prior to giving consent through a Consent Form (Attachment 4). Research personnel will provide answers to any questions potential subjects may have prior to consent. Consenting will take place in the Communication building room 304 or 308 with only study personnel and the subject present.

Following the experimental task, research personnel will debrief each subject roughly following the script in Attachment 5 for the purposes of answering any questions the subject may have, noting any problems the subject experienced, and to reiterate the aims of the research.

7) Procedures involved in the Human Research

Participants will fill out a survey recording the handedness of certain blood relatives as well as their own handedness (Attachment 6).

Participants will be fitted with an electrode net to noninvasively record brain activity during one or more of the following behavioral tasks. The electrode net consists of small sponges wired together in an elastic cap. Caps come in three sizes to comfortably fit a range of head sizes. Prior to fitting the net, the net is soaked in an electrolyte solution and then patted dry. Electrical contact is made through the conductivity of wet sponges touching the scalp. No gels are used. Fitting and testing the net will take about 10-20 minutes.

During the experimental task, participants will hear a series of notes played through stereo speakers. Most notes will be played by the same instrument. Participants will monitor the musical sequence and press a button whenever a note is played by a different musical instrument. This portion of the study will take between 30 and 60 minutes.

8) Risks to subjects

Subjects may be fitted with an EEG net to noninvasively measure their brain activity. Researchers will be present during the experiment and will stop the experiment and remove the electrode net in the event of participant discomfort. As with any electronic device, there is a very small risk of electric shock from the equipment used in this study. The risk of electric shock is no greater than the use of any electronic equipment, such as a personal computer.

In the unlikely event of electric shock, the power to the EEG system and associated equipment will be cut off. The system will not be used until repaired and recertified by the manufacturer.

Appropriately sized EEG nets (small, medium or large) will be used to minimize discomfort. Discomfort can be immediately resolved by removing the net. All EEG equipment was designed under ISO 13485 quality system procedures, and has received FDA clearance for use with humans. Additionally, all electronic equipment is plugged into isolation transformers to isolate the equipment from the power supply. Nets will be disinfected after every use.

9) Potential benefits to subjects and/or society

No direct benefit is anticipated for subjects. Society may benefit indirectly through increased understanding of brain functioning and individual genetic variation.

10) Provisions to protect the privacy of subjects and the confidentiality of data

Protection of subject privacy: Identifying information for subjects will not be collected as part of this study.

Protection of data confidentiality: All data will be stored in lock file cabinets that are only accessible by research staff. Electronic copies of the data will be stored on password protected files on the hard drives of the research personnel and on back-up optical disks kept locked in the Communication building, rooms 304, 306, and 308, and to which only research personnel will have access, unless otherwise required by law. Data will not be destroyed because if it were, and such data were needed again, new subjects would have to be inconvenienced to re-collect the data, and the data presents no danger to subjects even if it were to become public.

11) Cost to subjects

The only cost to subjects is up to 1.5 hours of their time.

12) Subject compensation

Subjects recruited from the Psychology subject pool will receive course credit for participating in this study. These subjects will have the opportunity to complete other educational tasks instead of participation. Volunteer subjects will not be compensated.

13) Withdrawal of subjects

Subjects may discontinue participation at any time with no increase of risk.

14) Sharing of results with subjects

Subjects can learn about the results of the study by contacting the PI following the completion of the study.

15) Drugs, Devices, and Gases

This project will employ Electric Geodesic, Inc.'s Geodesic Electroencephalographic System with a HydroCel Geodesic Sensor Net (GSN).

This medical equipment is certified to EN 60601-1, CAS 22.2 No. 601.1, CSA 22.2 No. 601.2.26, UL 2601, and IEC 60601-2.26. The Geodesic EEG System, of which the GSN is a part, carries the US FDA Pre-market 510k Clearance K012079 (Attachment 7).

Only research personnel qualified by training materials furnished by the device manufacturer will control the device's use at all times. The device will be used, cleaned, and stored in Communication 304 in accordance with practice recommended by the device manufacturer. Only qualified research personnel will use and have access to the device, since Communication 304 is locked at all times. The device is not to be disposed of, but regular cleaning and minor repairs will be carried out by qualified research personnel. Major maintenance and replacement of the device is carried out by the manufacturer on a yearly basis.

SECTION 4: LIST OF ATTACHMENTS FOR THIS SUBMISSION	
Document Name	**Version Date**
1. PI Curriculum Vitae	**1.**
2. F107 VOTF	**2.**
3. Recruitment Scripts	**3.**
4. Consent Form	**4.**
5. Debriefing Script	**5.**
6. Familial Handedness Questionnaire	**6.**
7. Geodesic Sensor Net FDA 510k clearance	**7.**
8. Geodesic Sensor Net Manual	**8.**

FORM: Verification of Human Subjects Training Form (VOTF)		
NUMBER	**FORM DATE**	**PAGE**
F107	01/2014	1 of 1

- **Only electronic submissions will be accepted**

Use to list all current Key Personnel			
IRB Project No.:		**Date:**	
Project Title:	Neurology of Musical Grammaticality in Trained Musicians		
Investigator:	Thomas G. Bever		
Investigator's Contact Information:	Official University Email: tgb@email.arizona.edu Phone: 520-626-6366		
Alternate Contact:	Daniel Carrera		
Alternate Contact's Information:	Official University Email and UA NetID: dcarrera Phone: 602-859-1014		

Name	UA Net ID	Research Role	Department & Institution	Consenter	CITI Training Date
[redacted]	[redacted]	PI	UA Linguistics	☒ Yes ☐ No	4/9/2013
[redacted]	[redacted]	UGRA	UA Mind, Brain, and Behavior	☒ Yes ☐ No	1/21/2014
[redacted]	[redacted]	GRA	UA Linguistics	☒ Yes ☐ No	1/24/2011
[redacted]	[redacted]	UGRA	UA Mind, Brain, and Behavior	☒ Yes ☐ No	4/9/2013
[redacted]	[redacted]	UGRA	UA Mind, Brain, and Behavior	☒ Yes ☐ No	2/14/2014
[redacted]	[redacted]	UGRA	UA Linguistics and School of Art	☒ Yes ☐ No	2/22/2014
				☐ Yes ☐ No	
				☐ Yes ☐ No	
				☐ Yes ☐ No	
				☐ Yes ☐ No	
				☐ Yes ☐ No	
				☐ Yes ☐ No	

APPENDIX 3

SAMPLE RECRUITMENT MATERIALS

The following are sample texts that will be used for recruiting subjects. It is possible that the actual texts will vary slightly from what is written below. However, the main ideas in each text will remain the same.

A. RECRUITMENT/PRESCREENING EMAIL:

[Included for participants recruited from the mass survey]
You are being invited to participate in studies of cognitive processing based on information you provided on the mass survey in your PSY 150A1/101 course.

[Included for self-selecting participants]
Thank you for your interest in participating in experiment #<experiment number>.

[Included for all potential participants]
The experiment consists of one session that will last up to 1.5 hours. During the experiment, you will listen to musical chords and respond when you hear the musical instrument change. During these tasks, your brainwaves may be recorded through an electrode net worn on your head. You will receive course credit for your participation.

To determine your eligibility, please reply with your answers to the questions below. A researcher will review your responses and contact you if needed. If you do not wish to participate, simply ignore this email.

If you have questions about the study, please contact a researcher by replying to this e-mail or calling 520-626-6593. You may also contact the principal investigator, Thomas G. Bever, directly at tgb@email.arizona.edu.

This study involves the use of EEG recordings, a non-invasive way of measuring the activity of your brain. During the study, you may be fitted with an electrode cap soaked in an electrolyte solution. Certain conditions may make the study procedures difficult or increase your risk of being irritated by the electrolyte solution. To ensure that you are eligible to complete the study, please answer the questions below. If you do not want to answer a question, you may state that or decline to return the questionnaire. This information will be used only for screening purposes.

1. When is your birthday? Please give month, day, and year.
2. Do you have normal hearing?
3. Have you had musical training, or do you play an instrument? How long have you played?
4. Do you have any history of head trauma or neurological problems (e.g. loss of consciousness, epilepsy)?
5. Have you ever been diagnosed with a psychological/psychiatric disorder? If so, what

was the diagnosis and are you currently being treated?
6. Do you currently have an open head wound?
7. Are you currently taking any prescription psychopharmacological medications? These are drugs that are prescribed for or may affect psychiatric conditions, such as Ritalin or other drugs for ADHD/ADD, anti-depressants, anti-anxiety drugs, beta blockers (also used for blood pressure regulation) and anti-psychotics.
8. Do you have a tightly braided (e.g. cornrows) or other hairstyle that would make contact with the scalp difficult that you would be unwilling or unable to take down for the study?
9. Is your hair dyed? If so, what color is it dyed?

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

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Language and Cognition Lab
Communication 304
520-626-6593

B. INFORMATION TO APPEAR ON THE SONA EXPERIMENT WEBSITE MAINTAINED BY THE PSYCHOLOGY DEPARTMENT

The experiment consists of one session that will last up to 1.5 hours. During the experiment, you will listen to musical chords and respond when you hear the instrument change. During these tasks, your brainwaves may be recorded through an electrode net worn on your head. You will receive course credit for your participation.

If you have questions about the study, please contact a researcher by sending an email to dcarrera@email.arizona.edu or calling 520-626-6593. You may also contact the principal investigator, Thomas G. Bever, directly at tgb@email.arizona.edu.

C. FOLLOW-UP EMAIL SCRIPT (ELIGIBLE):

Thank you for your interest in our studies.

To participate, please log on to http://experiments.psychology.arizona.edu and select our study.

You may sign up for experiment # [website experiment number] using the password '[study password]' (do not include the quotes).

If you do not wish to participate, simply ignore this email.

If you have questions about the study, please contact a researcher by replying to this e-mail or calling 520-626-6593. You may also contact the principal investigator, Thomas G. Bever, directly at tgb@email.arizona.edu.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

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Language and Cognition Lab
Communication 304
520-626-6593

D. FOLLOW-UP EMAIL SCRIPT (INELIGIBLE):

Thank you for your interest in our studies. Unfortunately, we cannot accommodate your participation at this time.

If you have questions about the study, please contact a researcher by replying to this e-mail or calling 520-626-6593. You may also contact the principal investigator, Thomas G. Bever, directly at tgb@email.arizona.edu.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

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Language and Cognition Lab
Communication 304
520-626-6593

The University of Arizona Consent to Participate in Research

Study Title: **Neurology of Musical Grammaticality in Trained Musicians**

Principal Investigator: **Thomas G. Bever**

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

You will not directly benefit as a result of participating in this study. Also, as explained below, your participation may result in minor unintended or harmful effects the risk of which is no greater than that of everyday life.

1. Why is this study being done?

The purpose of this study is to examine similarities in processing musical and linguistic structures in trained musicians.

2. How many people will take part in this study?

Up to 60 people will take part in this study.

3. What will happen if I take part in this study?

You participation will last up to 1.5 hours and include one session.

You will be fitted with an electrode net to noninvasively record your brain activity during one of the above-described behavioral tasks. The electrode net consists of small sponges wired together in an elastic cap. Caps are of three sizes to comfortably fit a range of head sizes. Prior to fitting the net, the net is soaked in an electrolyte solution and then patted dry. Electrical contact is made through the conductivity of wet sponges touching the scalp. Fitting and testing the net will take about 10-20 minutes.

When the experiment begins, you will monitor a series of notes for changes in the instrument used to play the note. Whenever you detect a change, press a button. The experiment will start with a practice session to familiarize you with the task. The decision task will take between 30 and 60 minutes.

4. How long will I be in the study?

Your participation will be limited to a single visit lasting no longer than 1.5 hours.

5. Can I stop being in the study?

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

6. What risks, side effects or discomforts can I expect from being in the study?

The risks of participating are minimal. If you do experience discomfort, you will be allowed to take breaks during the completion of study assessments to minimize discomfort, and as always, you may discontinue participation in the study at any time with no loss of benefits to which you are otherwise entitled.

If you choose to participate, you will be in contact with electrical equipment, which as in everyday life carries a small risk of electric shock. The risk of shock is no greater than the use of any electronic equipment, such as a personal computer. Additionally, all electronic equipment is plugged into medical-grade isolation transformers to prevent a power surge or other problem with the building electrical supply from reaching you.

If your scalp's electrical activity is measured using an electrode net, your hair may be slightly damp and salty after the experiment and you may want to wash your hair after participating. A few electrodes placed on your face may leave visible impressions. These will disappear 5-10 minutes after the net is removed.

7. What benefits can I expect from being in the study?

No direct benefits are anticipated from being in the study.

8. What other choices do I have if I do not take part in the study?

The alternative to participating in this study is to choose another eligible study to participate in or to complete an alternative assignment as described in your course syllabus. You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal

information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies
- The University of Arizona Institutional Review Board or Office of Responsible Research Practices
- The sponsor supporting the study, their agents or study monitors
- The University of Arizona Health Network (UAHN)

Your name and other identifying information will not be linked to study data at any time. Research personnel for the study will have access to your name on the Psychology Department's Experiment Scheduling and Tracking System website for the purpose of assigning course credit, but every identifying record of your participation will be automatically expunged at the end of the current semester.

10. What are the costs of taking part in this study?

There are no costs of taking part in this study apart from your time.

11. Will I be paid for taking part in this study?

No, you will not be paid for taking part in this study. If you are enrolled in PSY 101 or 150, you will receive 1 credit per half hour of participation, up to 3 credits. If you are participating on an individual basis, you will not receive compensation for participating.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the principal investigator, Thomas G. Bever, at tgb@email.arizona.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at http://orcr.arizona.edu/hspp.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact principal investigator, Thomas G. Bever, at tgb@email.arizona.edu.

By continuing with this research project you are allowing your data to be used for research purposes.

NEUROLOGY OF MUSICAL GRAMMATICALITY IN TRAINED MUSICIANS

The script below is an example of what would be said during the debriefing. Because of the natural variation in conversation, the actual utterances may vary. However, the key ideas expressed in this example will be present in every variation on the script.

SAMPLE SCRIPT FOR DEBRIEFING SUBJECTS AFTER THE EXPERIMENT

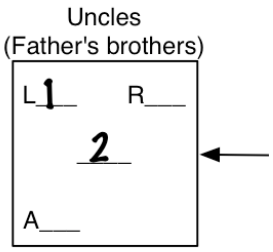
In brain studies of language and music, there is individual variation in how much neural activation occurs and where it occurs in the brains of the participants. One source of this variation is whether the (right-handed) participants have left-handed family members (in which case we call them "FS+") or not (in which case we call them "FS-").

A previous study showed that the pattern of brain activation differed in FS+ and FS- people when they heard unusual chord sequences like what you heard. FS- people tended to have a big spike of electricity from neurons firing in the **right** front part of the brain, while FS+ people tended to have a similar spike in the **left** front part of the brain. In either case, the spike happened about the same time, which was "early", about 200 milliseconds after the unusual chord was heard.

This difference is the opposite of what happens when people are played certain kinds of ungrammatical sentences instead of unusual chord sequences. That is, if an FS- person hears a sentence like "The girl *in* saw the boy", then their brain will react with a negative spike in the **left** front part, whereas an FS+ person's brain would have a negative spike in the **right** front part.

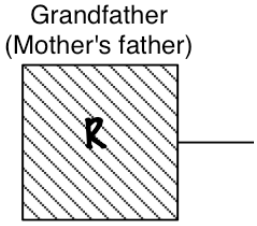
This study's goal is to see whether similar results to the previous music study are found when the listener has had extensive musical training. It is possible that musicians would not react the same way to the unusual chord sequences because of their different experience. For example, musicians' brains may have a much smaller effect overall, having heard a wider range of chord sequences and therefore being used to the change. They may instead have a different pattern of brain activation because they do not hear the sequence as an error. Or they may have a much larger effect, being sensitive to expected sequences and having their prediction foiled.

Please read and follow these directions carefully. On the following page is a family tree. It shows your father's side of the family on the left and your mother's side on the right. For each relation in the tree, think carefully about your BLOOD relatives. In the center of the box, write in the TOTAL number of people related to you in that position. Then write in the NUMBER of relatives who are Left-handed, Right-handed or Ambidextrous (use both hands about equally well) in the spaces provided.

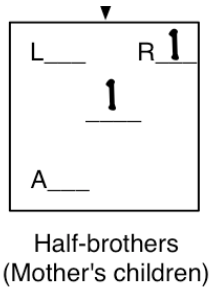


For example, I have three uncles, all on my father's side. Only two of my uncles are blood relatives (my father's brothers); the third is married to my father's sister and so is not a blood relative. Of the two uncles, I know one is left-handed and am unsure of the other's hand preference.
I would fill in the Uncles box on the left of the page (my father's side of the family) as shown here.

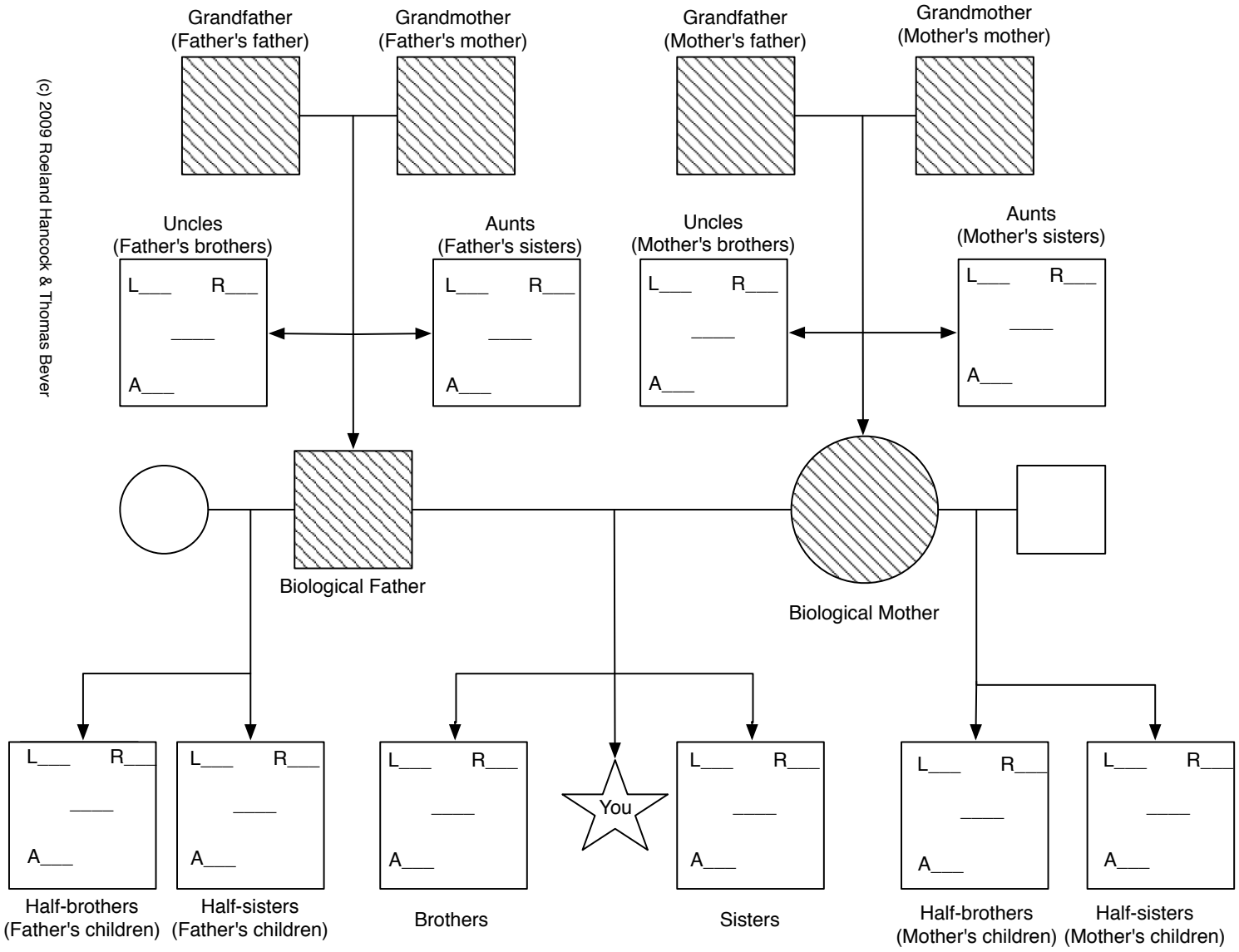
The boxes with diagonal lines correspond to one person in your family tree. For these boxes, write in that person's hand preference (L, R or A). Leave the box empty if you are unsure of their hand preference. For example, my grandfather on my mother's side is right-handed, so I would fill in the box like this:



There are also spaces for half-siblings, the biological children of one, but not both, of your biological parents. For example, my mother has a male child from a previous partnership. I know my half-brother is right handed, so I would fill in the box like this:



Please let the experimenter know if you have any questions.



Subject ID_____ Sex_____ Initials_____ Date_____ Identical Twins:_____

SEP 1 9 2001

[redacted]

510(k) SUMMARY

Submitter's name: Electrical Geodesics, Inc.
1850 Millrace Drive
Eugene, OR 97403
541-687-7962

Date summary prepared: June 25, 2001

Device name:

Proprietary name:	Geodesic EEG System™
Common or usual name:	EEG machine
Classification name:	Electroencephalograph, 84 GWQ Class II, 21 CFR 882.1400.

The product includes the Geodesic Sensor Net® which has the following identifiers:

Common name:	EEG electrode
Classification name:	Cutaneous electrode, 84 GXY Class II, 21 CFR 882.1320.

Legally marketed device for substantial equivalence comparison:

For the Geodesic EEG System it is the Bio-Logic Ceegraph 128-Channel Recording System submitted by Bio-Logic Systems Corporation and cleared for marketing under 510(k) #K973883. For the Geodesic Sensor Net, the predicate device is the Electro-Cap VII System submitted by Electro-Cap Inc. and cleared for marketing under 510(k) #K780045.

Description of the device:

The Geodesic EEG System is a digital electroencephalography system (EEG) with a dense sensor array of 32 to 256 channels. Like existing digital EEG systems, the Geodesic EEG System is computer controlled and capable of acquiring, storing, and displaying data. It includes scalp conductive electrodes, amplifiers, a central processing unit, and software. The Geodesic Sensor Net is a dense array of scalp electrodes designed to allow rapid application in an even distribution across the head. The Net Amps™ consists of multiple amplifiers for physiological signals that are fully software controlled. Net Station® is the software package that provides control of the Geodesic EEG System, digital data storage, and operator-selected waveform displays. The software does not perform any data analysis. Additional components of the system are an articulated arm with extended cable, rack system, various cables, standard components of personal computer (monitor, keyboard, mouse), electrolyte solution, and disinfectant.

The Geodesic EEG System is a new device that has not previously been submitted to FDA. It has features similar to other digital EEG devices on the market.

Intended use of device:

The Geodesic EEG System is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

Technological characteristics:

The technological characteristics of the Geodesic EEG System are similar to those of other digital EEG systems, including the predicate device, the Ceegraph 128-Channel Recording System. Each product is an EEG machine that is software controlled, can accommodate a variable number of electrodes, and can acquire, display, and record EEG data. Some differences in electrical parameters are described. Differences in the software include that the products use different operating systems and that Net Station does not analyze the data. Another difference is that the Geodesic EEG System has dedicated electrodes, the Geodesic Sensor Net.

The Geodesic Sensor Net is compared to the Electro-Cap VII System. Each product consists of a structure that links a number of electrodes so that they can be easily applied to the patient. The Geodesic Sensor Net uses a geodesic array of electrodes with equal distribution across the head. The Electro-Cap uses the 10-20 array. The Geodesic Sensor Net can accommodate a larger number of electrodes. Finally, the Geodesic Sensor Net does not require scalp abrasion for use.

Testing conducted:

Testing was conducted to ensure compliance with international standards related to electroencephalographs. The general safety standards used were: CAN/CSA C22.2 No. 601.1-M90 including Supplement 1 and Amendment 2 and UL Std. No. 2601-1 (2nd Edition). The electromagnetic compatibility standard was EN60601-1-2(1993). The electroencephalograph standards were IEC 60601-2-26 and CAN/CSA C22.2 No. 601.2.26. The biocompatibility standard was ISO 10993. The Geodesic EEG System passed all testing.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Electrical Geodesics, Inc.
c/o Mr. Robert S. McQuate
R. S. McQuate & Associates, Inc.
3636 E. Columbine Drive
Phoenix, Arizona 85032

Re: K012079
Trade/Device Name: Geodesic EEG System™
Regulation Number: 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: June 29, 2001
Received: July 3, 2001

Dear Mr. McQuate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

[redacted]

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): [redacted]

Device name: Geodesic EEG System™

Indications for Use:

The Geodesic EEG System is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

[redacted]

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number [redacted]