CUREB A&B: Research Ethics Submission Form

Top of Form

1. Project Team

1A. Lead Researcher

(Detailed instructions)

	Academic Staff
	Library or Other Staff
	Post-doctoral Fellow
	Ph.D. Student
	Master's Student
X	Undergraduate
	Student Association/Club
	Other

Last name/First name

Response: Sharan, Kabir

Official university (or other institution) email address:

Response: kabirsharan@cmail.carleton.ca

Indicate your department, faculty and institution

Response: Faculty of Engineering, Department of Mechanical and Aerospace Engineering at Carleton University

1B. Academic Supervisor

(Detailed instructions)

	Same as lead researcher

Academic supervisor(s) Last name/First name. (Note, the supervisor must be copied on all correspondence with CUREB.)

Response: Chan, Adrian

Official university (or other institution) email address:

Response: adrian.chan@carleton.ca

Indicate your department, faculty and institution

Response: Faculty of Engineering, Department of Systems and Computer Engineering at Carleton University

1C. Project Team Members

(Detailed instructions)

	Not applicable/No other team members

List the project team members here. For each team member, provide the following: 1) Last name/First name 2) Email address 3) Role in project 4) Department and institution (E.g. Master's student in Canadian Studies at Carleton)

Issa, Tarek, tarekissa3@cmail.carleton.ca, researcher, Undergraduate student in the Department of Mechanical and Aerospace Engineering at Carleton University

Vasudev, Brayden, braydenvasudev@cmail.carleton.ca, researcher, Undergraduate student in the Department of Mechanical and Aerospace Engineering at Carleton University

Hayles, Joshua, joshhayles@cmail.carleton.ca, researcher, Undergraduate student in Department of Systems and Computer Engineering at Carleton University
Rocco, Adam, adamrocco@cmail.carleton.ca, researcher, Undergraduate student in Department of Systems and Computer Engineering at Carleton University

1D. TCPS Tutorial

	Have not completed the online TCPS tutorial
X	Completed the online TCPS tutorial

It is recommended that researchers complete the TCPS tutorial (www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel)

Response: The TCPS tutorial has been completed.

1E. Researcher Training
(Detailed instructions)

	No training provided/Not applicable
X	Researcher will be trained
	Researcher is trained

Describe any additional training the researcher(s) have (or will receive) to work with the participants.

Response: Researchers will be trained to use a BioRadio.

2. Study Overview

2A. Project Title
(Detailed instructions)

Title of Research Project

Response: Effects of Stress induced by different music genres on Heart Rate Variability

2B. Study Goal
(Detailed instructions)

What question will your research answer (1-2 sentences)?

Response: How does stress induced by music affect heart rate variability?

2C. Study Purpose and Benefits
(Detailed instructions)

Study rationale: why should the research be pursued; what are the benefits, and to whom? (Benefits can be to research community, companies, or society in general.)

Response: The benefit of the research is to further knowledge of the effect of of stress on heart rate variation when induced by different genres of music.

2D. Dates of Recruitment/Participant Interaction
(Detailed instructions)

	Not applicable/Secondary Data

When will you start recruiting participants? (DD/MM/YYYY)

Response: 13/02/2019

When will you stop interacting with participants? (DD/MM/YYYY)

Response: 15/03/2019

2E. New or Previously Recorded Data
(Detailed instructions)

X	New Data
	Secondary Analysis of Anonymous Data
	Secondary Analysis of Coded or De-identified Data
	Secondary Analysis of Directly Identifying Data

Does this research collect new data or analyse previously collected data (secondary analysis)? If the research involves secondary analysis, describe the coding of the data. (Note, secondary analysis requires ethics clearance, except when data are truly anonymous)

Response: Data will be collected during this research.

2F. Additional Reviews
(Detailed instructions)

X	No additional review
	Departmental review
	Grant council review

Has this project been reviewed for academic merit, and by whom (e.g. as part of a tri-council grant application or student's thesis committee)?

Response: N/A

3. Funding and Approvals

3A. Project Funding
(Detailed instructions)

X	Unfunded
	Tri-Council Funded
	Other Award/Grant
	Contract Funded
	Personal Consulting or Personal Work
	Scholarship

Who is funding this project? If applicable, include the funding source/agency/company, program, and award name and number (from CUResearch)

Response: N/A

3B. Researcher Funding (for research contracts and personal consulting only)
(Detailed instructions)

X	Not applicable/Not contract funded research

For research contracts and personal consulting only: how much of the funding for this project is going directly to the researcher(s) as income? Include the dollar amount and the percentage of the total funding amount. Will this create a real or perceived conflict of interest and how will it be managed? Provide the title and date of any contracts. (The REB may review the contract.)

	No funds are paid directly to the researcher as personal income
	The researcher will receive a portion of the funds as personal income
	A copy of the contract/agreement has been submitted to the Research Compliance Office

Response: N/A

3C. Minimal Risk Review Request
(Detailed instructions)

	No
X	Yes

Would you like to request this protocol be considered for minimal risk review? If so, please briefly justify. If not requesting a minimal risk review, leave this section blank. (The REB will use this information to make a decision as to whether this application will be reviewed at full board or via a delegated process)

Response: There is a small risk of irritation from the electrode on the participant's skin. Irritation can be present in a person's everyday life due to allergies. There is a very small risk of shock from the bioradio used as it is battery powered. This type of shock can be experienced by any electrically powered device that a participant would use in their everyday life. For example, a participant's phone, remote, or computer could deliver a small shock that is not deadly. Stress is being induced in the participants which could lead to unexpected physiological problems. If an incidental finding is found, the participant may have some psychological harm due to unexpected news. A small chance of auditory irritation can occur if the volume is too loud while listening to the music. These risks are very unlikely and are similar to risks participants would be exposed to in everyday life so the research should be considered minimal risk.

3D. Additional Approvals Required
(Detailed instructions)

X	Not applicable/No other approvals required
	Organizational Permission
	Visa/Travel Permits

Is organizational permission required to conduct research (i.e. schools, employers, correctional services, aboriginal communities). If conducting research in another country, is local permission required? Indicate if permission has been secured and provide a copy of the permission. Research with biohazards or animals must also secure approval from the appropriate committee at Carleton University.

Response: N/A

	Other REBs or Institutional Approvals
	Biohazards
	Animal Care Committee
	Other (please specify)
	Permission letters attached
	Letters to follow

4. Methods: Participants

4A. Participant Interactions Overview
(Detailed instructions)

X	Directly interacting with participants
	Interacting with participants online (e.g. online surveys)
	Observing participants
	Secondary Analysis of Data
	Other

Briefly list what will happen to, or will be required of, the participants during the course of the research. Break down by phases if required. (Only a project overview is requested here; methodology details are required in the first question of each section). If the research involves secondary analysis of data that has already been collected, the REB needs information about the original data collection to be confident data were collected ethically.

Response: A mass email will be sent to students attending Carleton University asking for volunteers to participate in the experiment. The contents of this email can be found at the end of this document. Participants who want to participate must send an email to the researchers indicating so. Once a scheduled time is set for the researchers to meet with the participant for the study, a full explanation the process of collecting data will be explained along with the risks. A consent form will then be given to them to sign if they are still willing to participate. To begin, a wet wipe will be used to sterilize and clean the participant's skin where electrodes will be placed to connect to the Bioradio so the ECG can measure their heart rate. Then their heart rate at rest will be recorded to use as a control. Then the participant will place a set of noise cancelling headphones to listen to the classical music. Once the data is collected for the classical music sample, **a couple of minutes will pass and then** rock music will be played. The test will be complete once the data for the rock music sample is recorded. After the test is over, the electrodes and headphones will be removed from the participant and they will be compensated with candy. The participant can withdraw from the study at any point during the data collection and up to 24 hours after their session. Interaction with the participant during the experiment will take at least 30 minutes.

4B. Description of Participants
(Detailed instructions)

Describe the participants and any inclusion criteria. If applicable, describe any exclusion criteria. If using a separate sample of control participants, describe this group.

Response: Participants must be at least of age 18. Participants must also have no flu like symptoms as these would change how hard the participant's heart would be working. The participant must also not have any known pre existing heart condition. Participants with known hearing impairment must be excluded from this research due to the auditory nature of the stressor.

4C. Number of Participants
(Detailed instructions)

What is the number of participants requested? Provide a justification including a statistical rationale if appropriate.

Response: A total of 20 participants with 10 being male and 10 being female is requested. 20 participants would be a large enough amount to draw significant conclusions from the data.

4D. Vulnerable Population
(Detailed instructions)

X	Not Vulnerable Population
	Vulnerable Population

Describe any pre-existing vulnerabilities associated with the proposed participant group(s) that may cause additional risks. Describe the associated risks and mitigation strategy.

Response: N/A

4E. Participant Relationship to Researcher
(Detailed instructions)

	No previous relationship
	Instructor-Student
	Client
	Employee
X	Friends/Family
X	Other

Describe any relationship that exists between the participants and the research team or any recruiting party or sponsor. Indicate how relationships will be managed so there is no undue pressure put on participants.

Response: Due to all the researchers being students at Carleton University, it is possible that some of the participants that offer to take part in the experiment may have a prior relationship with the researchers. This could be due to student interactions from being in the same classes. The email will be sent in mass to a random list of students where the contents are not targeting any one individual. The participants will be contacting the researchers at their own free will, therefore no pressure will be put on participants to join. The email will also be bcc so that the number of participants is unknown to the recipient so that they do not feel pressure to join or not.

4F. Conflict of Interest
(Detailed instructions)

X	No conflicts
	Financial
	Commercial Entity Benefits
	Other

Describe any real or perceived conflicts of interest for any research team member that could affect participant welfare. If so, describe it here and indicate how it will be managed.

Response: N/A

5. Methods: Recruitment

5A. Recruitment Methods
(Detailed instructions)

	Not applicable
	Posters
	Social Media
	Online Panels (e.g. Qualtrics)
	Student Participant Pool (e.g. SONA)
X	Emails
	Letters
	Telephone
	Snowballing
	Other

Describe each step of how participants will be recruited. This includes how contact information is obtained, how participants will be made aware of the study, where will recruitment materials be located, and how participants can express their interest. Provide a copy of the recruitment material(s) including any oral scripts, recruitment posters, recruitment emails, social media postings etc.

Response: An blind carbon copied mass email will be sent to random students from Carleton University asking for volunteers to be participants in a heart rate variability experiment. If they are willing to participate, they will need to contact one of the researchers by email. Emails will be obtained from class lists on cuLearn that is accessible by anyone in the course. We would then explain the experiment as well as the entire procedure with detail. If they chose to participate we will schedule them and provide an even further explanation as well as a consent form, and then we would proceed with the experiment.

5B. Location of Recruitment
(Detailed instructions)

	Not applicable
	Carleton
	Other Canadian School/University
	Canada
X	Online
	Other

List all recruitment locations. If some locations require permission prior to recruitment, indicate if permission has been secured.

Response: Recruitment will take place through carleton email services.

5C. Third Parties in Recruitment
(Detailed instructions)

X	Not applicable
	Third Parties

If using third parties to recruit, indicate who is doing the recruitment and how it will be accomplished. Does the third party have contact information for the participants? If not, how will it be acquired?

Response: N/A

5D. Recruitment risks to Participants
(Detailed instructions)

X	No risks / Not applicable
	Mild risks

Describe any risks to participants during the recruitment phase.

Response: There would be no added risk other than what they would experience in daily life during recruitment.

	Moderate risks
	Extreme risks

5E. Recruitment risks to Researcher
(Detailed instructions)

X	No risks / Not applicable
	Mild risks
	Moderate risks
	Extreme risks

Describe any risks to the research team during the recruitment phase.

Response: N/A

5F. Benefits
(Detailed instructions)

	No benefits / Not applicable
	Benefits to Society/Knowledge
X	Benefits to Participants

Describe any direct benefits to the research participants.

Response: The participants may gain knowledge about their heart or about how ECGs work.

5G. Compensation
(Detailed instructions)

	No Compensation/Not applicable
	Money / Gift Card
	Reimbursement of Travel Expenses
X	Refreshments
	Course Credit
	Other

Describe all compensation/remuneration and indicate when participants will receive the compensation. What is the monetary value of the compensation/remuneration? What happens to the compensation if a participant withdraws?

Response: Candy with a max valuation of 2$ will be given to each participant. The compensation will be given at the end of the session after the data has been collected. If a participant withdraws during the session, they will still receive compensation. Bottles of water will also be provided during the session.

6. Methods: Informed Consent

6A. Obtaining informed consent
(Detailed instructions)

X	Signed consent
	Online consent
	Oral consent
	Implied consent
	Parent/Guardian consent
	Assent

Describe the method for obtaining informed consent from the participants. Justify the method chosen. Include a copy of the consent materials.

Response: Once a potential participant has been selected, a written consent form will be emailed to them to review in advance. If they agree, they will sign the form in person before the study is conducted. The entire process of what will occur during the test and what risks will be presented will be on the form.

	Other

6B. Deception
(Detailed instructions)

X	No deception
	No risks
	Mild risks
	High risks

Describe the nature of the deception, what information will be withheld, and justify why it must be used to achieve the research goals. Describe the magnitude and likelihood of harm due to deception.

Response: N/A

6C. Debriefing
(Detailed instructions)

X	Not applicable/not required
	Participants will be debriefed

When and how will participants be debriefed? (Include a copy of any documents that will be provided to participants). Describe any risks during debriefing and how they will be mitigated. According to the TCPS2, debriefing is required in all cases of deception: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1b

Response: N/A

6D. Withdrawal Procedures
(Detailed instructions)

	Not applicable
X	Participants can withdraw
	Participants can only withdraw during the study
	Special withdrawal procedures

Describe the procedures for a participant to withdraw. What will happen to data from participants who withdraw? Describe any deadlines and limitations on withdrawal.

Response: Withdrawal can occur at any point during the session and until 24 hours after the session. To withdraw during the data collection, participants must verbally state that they do not want their data to be part of the research. Once their data has been collected, to withdraw they must send an email stating they do not want their data to be part of the research. Once withdrawn, the data will be destroyed.

7. Methods: Data Collection

7A. Data Collection Methods
(Detailed instructions)

	Questionnaires / Surveys
	Interviews
	Focus Groups
	Oral and/or Visual Stimuli
X	Equipment and/or software testing
	Other

Describe the method of data collection being used and provide details of any instruments used. (CUREB requires a copy of any questions or themes being posed.) If data collection is being done online, visit the detailed instructions for full details on what information the REB requires. Attach a copy of the questionnaire to the application.

Response: To measure the heart rate variability, a wearable and portable physiology monitoring device will be used. The device is called Bioradio and is manufactured by Great Lakes NeuroTechnologies (Part Number: 700-0016-BK). Ag/AgCl electrodes, attached to the participant, will capture biosignals and send them to the BioRadio. Using bluetooth, the BioRadio will send the biosignals to an ECG connected to a computer. On the ECG, the

heart rate will be analyzed for variation by measuring the distance between the peaks of the R-R waves between heart beats. This data will then be kept on a spreadsheet on a google drive only accessible by the researchers.

7B. Location of Data Collection
(Detailed instructions)

X	Carleton
	Canada (other than Carleton)
	Workplace
	Public venue
	Online
	Other

Where will the participant be during data collection?

Response: The participants will be at Carleton in a laboratory setting during data collection.

7C. Photography or Recordings
(Detailed instructions)

X	Not applicable
	Photographs
	Audio Recording
	Video Recording

If the participant will be photographed, video-recorded or audio-recorded, indicate how the data will be acquired and protected (if applicable).

Response:N/A

7D. Translation or Transcription
(Detailed instructions)

X	Not applicable
	Translation
	Transcription
	Researcher will translate or transcribe

If you require the services of a translator or transcriber, describe what services you will use and how you will interact with the translator and/or transcriber. If a confidentiality agreement will be used, include a copy.

Response:N/A

7E. Online data collection
(Detailed instructions)

X	Not applicable
	Carleton-based server
	Commercial server (based in Canada)
	Commercial server (outside Canada)
	Other

Describe the technology platform used to collect online data. Describe the security of the data. Will participant IP addresses recorded? Are there any special limits to privacy?

Response:N/A

7F. Bio-interactions
(Detailed instructions)

X	Not applicable
	Biological specimens/fluids

Describe the apparatus and methods to acquire biological specimens or fluids. (e.g., blood, saliva, tissue samples.) How will specimens be safely stored and destroyed? If any will be kept, explain why, how and for how long.

Response: N/A

7G. Bio-instruments
(Detailed instructions)

	Not applicable
X	Bio-instruments

Bio-instruments touch or send energy into the body. (e.g., electrodes, MRI/X-ray.) Describe the apparatus and its use. If applicable, explain any significant risks and compare the dose (e.g., electrical, radiation) to established safety standards.

Response: The apparatus used is a BioRadio, which is a portable and wearable physiology monitor, that is rechargeable, that sends biosignals taken from the patient to an ECG using bluetooth. The device is connected to electrodes that attach to the subject and detect electrical impulses made by the heart from the arteries found in the wrists. An extremely small risk of shock may occur if the electrodes are attached to the participant and the device is attached to the computer to charge. To avoid this, the device will not be used if it is charging in the computer. The electrodes may cause temporary rash to some people. If it occurs, the participant will be given lotion to manage the discomfort.

7H. Bio-interventions
(Detailed instructions)

	Not applicable
X	Bio-interventions

Describe the apparatus and methods associated with the bio-intervention. (e.g., drug, stress, medical devices.) Explain any risks to the participants and compare it to established safety standards.

Response: The participant will be connected to the BioRadio with two leads about 7 inches apart and about an inch below the clavicle. The participant will also be wearing headphones and music will be played. The music is being considered a stressor which will contain classical music which should decrease stress and rock music which should increase stress. The changes in stress caused by the different genres of music can cause fluctuations in heart rate and blood pressure, but this is assumed to be unlikely and will should be similar to what participants will experience in daily life.

7I. Risk of Psychological Harm
(Detailed instructions)

X	Not applicable/No risks
	Mild risks
	Moderate risks
	High risks

Explain the rationale for your selection, and, if applicable, explain the nature, magnitude and probability of the risks and how they will be mitigated.

Response: In the case of the ECG showing irregular results, one could have mild physiological trauma due to fear and shock, but we must insist we aren't doctors and can't in fact confirm anything. The risks were deemed insignificant because they are unlikely and would not put the participant in

any danger. If the participant begins to feel uncomfortable we will stop the experiment and continue when the patient deems themselves fit.

7J. Risk of Physical Harm
(Detailed instructions)

	Not applicable/No risks
X	Mild risks
	Moderate risks
	High risks

Explain the rationale for your selection, and, if applicable, explain the nature, magnitude and probability of the risks and how they will be mitigated.

Response: Mild skin irritation due to the adhesive on the electrodes is possible. If this occurs, the experiment will be stopped. There is also a possibility that unexpected health changes may happen due to inducing stress in the participant. These risks have been deemed to be mild as they cause no significant harm to the participant. The probability of these risks occurring is very low but if anything were to happen, the experiment would stop and CUSERT will be called and we will stay with the participant until they arrive. Germs could be passed from one participant to the next as the same pair of headphones will be used throughout the research. To avoid this, the headphones will be disinfected between participant use using a disinfectant wet wipe. **T**here may be a small possibility of auditory irritation due to volume of the music. This will be mitigated by having the volume low initially and asking the participant to signify if the volume is comfortable as the volume increases. The volume will never go over 50% of the volume bar.

7K. Risk of Social and/or Economic Harm
(Detailed instructions)

X	Not applicable/No risks
	Mild risks
	Moderate risks
	High risks

Explain the rationale for your selection, and, if applicable, explain the nature, magnitude and probability of the risks and how they will be mitigated.

Response: N/A

7L. Incidental Findings
(Detailed instructions)

X	Not applicable/No incidental findings anticipated
	Low probability
	High probability

Describe possible incidental findings (unanticipated discoveries that relate to the welfare of participants or others) and how they will be managed. Examples are becoming aware of abuse of a child, or imminent harm to a participant or third party. Your approach to managing any findings should also be described in the informed consent.

Response: There are no known previous incidents of heart conditions as that is part of our exclusion criteria. Although, we may discover an abnormality in the biosignal. **If an abnormality is suspected, data collection will be stopped immediately. The participant will be informed that the ECG looks abnormal but that the researchers are not trained healthcare professionals and thus cannot make an interpretation. We will also tell the participant that if they**

wish they can consult with a healthcare professional (e.g., medical doctor).

8. Methods: Data Storage and Analysis

8A. Identifiability of stored data

(Detailed instructions)

	Anonymous
	Pseudonyms/Coded
	Real participant names with data attributable
X	Real participant names with data non-attributable
	Different levels of anonymity for different groups of participants

Describe the identifiability of research data, including how pseudonyms will be assigned, if applicable. If there are different levels of anonymity for different groups, describe each level here.

Response: Participant data will be stored under codes. Codes will be generated in the order the participants arrive (ex. Participant #1, Participant #2, etc.). A record will be kept linking the participant's name to the coded name in case someone withdraws. Once the withdrawal period is over, the record keeping of participant name to coded name will be destroyed. A record of the participant names will be kept seperate of the data.

8B. Identifiability of published data

(Detailed instructions)

	Anonymous
	Aggregate data only
X	Pseudonyms/Coded
	Real participant names with data attributable
	Real participant names with data non-attributable
	Different levels of anonymity for different groups of participants

Describe the identifiability of data that will appear in publications, including how pseudonyms will be assigned, if applicable. If there are different levels of anonymity for different groups, describe each level here.

Response: The data used in the publications will correspond to the codes assigned to each participant during the study period. Codes will be generated in the order the participants arrive (ex. Participant #1, Participant #2, etc.).

8C. Data Storage (during the project)

(Detailed instructions)

	Encrypted
X	Password-protected
	Anonymous data
	Physical documents
	Other

How are data being stored and kept safe? Provide details for electronic data and hard copies if applicable.

Response: Data will be kept electronically on a google drive. Google drive is cloud server and will be password protected. If a leak were to occur, the drive would have no way of identifying which data belongs to which participant.

8D. Data Disposition (after the project)
(Detailed instructions)

	Retained by the researcher(s)
	Stored in a depository
	Archived
	Shared with research agreement
	Shared publically
	Returned
X	Destroyed

After project completion, describe how the data (confidential and non-confidential aspects) will be stored for future use, made publicly available, archived, returned to participants, or destroyed. If shared, with whom? Describe any restrictions on access. If destroyed, how long will the data be kept? Will personal identifiers and the actual data be destroyed at different phases? Will participant contact information be kept for future studies?

Response: The data will be kept until April 30 and then will be destroyed.

8E. Data Breach Risks
(Detailed instructions)

X	Mild risk to participants
	Moderate risk to participants
	Extreme risk to participants

Describe how likely a data breach is to occur and how it could affect the participants. If risks are significant, how will they be mitigated?

Response: A data breach is unlikely to occur unless the google drive were to be hacked. If a breach occurs, the data will not be attributable to the participants so there is very minimal risk to the participant.

9. Declarations

9A. Supervisor Approval

	Not applicable
	Supervisor Approved
X	Supervisor has not approved

For student projects, please indicate the date that the supervisor approved the application to go forward for REB approval. (All CUREB-A applications must copy the supervisor when submitting an application to ethics@carleton.ca. CUREB-B applications are automatically submitted to the supervisor through the online application system; therefore, the student must inform his/her supervisor that the application has been submitted so that the protocol may be approved by the supervisor and received by CUREB-B).

Response:

9B. Declaration #1

X	I agree

This ethics application accurately describes the research project or scholarly activity that I plan to conduct.

9C. Declaration #2

X	I agree

No recruitment or data collection for this protocol will commence before ethics clearance.

9D. Declaration #3

X	I agree

No changes will be made to the research project as described in this protocol will be made without receiving clearance from the Research Ethics Board.

9E. Declaration #4

X	I agree

The Research Ethics Board will be notified immediately of any alleged or real ethical breaches or concerns, adverse events, or participant complaints that arise during or after the course of this research project.

10. Comments

10A. Comments (optional)

Do you have any comments or suggestions on the form

Response: N/A

11. Office Use

11A. Office Use

Date Submitted for Review

Response:

Other information

Response:

Bottom of Form

Research Consent Form

Name and Contact Information of Researchers:

Kabir Sharan, Principal Investigator, Student, Carleton University, Faculty of Engineering and Design kabirsharan@cmail.carleton.ca

Brayden Vasudev, Student, Carleton University, Faculty of Engineering and Design braydenvasudev@cmail.carelton.ca

Tarek Issa, Student, Carleton University, Faculty of Engineering and Design tarekissa3@cmail.carleton.ca

Joshua Hayles, Student, Carleton University, Faculty of Engineering and Design joshhayles@cmail.carleton.ca

Adam Rocco, Student, Carleton University, Faculty of Engineering and Design adamrocco@cmail.carleton.ca

Supervisor and Contact Information:

Adrian Chan, Professor, Carleton University, Department of Systems and Computer Engineering adrian.chan@carleton.ca

Project Title

Effects of Stress induced by different music genres on Heart Rate Variability

Carleton University Project Clearance

Clearance #: ** *(this is the 6-digit # assigned to your study)* Date of Clearance: **

Invitation

You are invited to take part in a research project because you have expressed interest in participating. If you are under the age of 18, have any known heart conditions, and/or have any known hearing problems, you may not participate in the research. The data collection should take at most 20 minutes. The information in this form is intended to help you understand what we are asking of you so that you can decide whether you agree to participate in this study. Your participation in this study is voluntary, and a decision not to participate will not be used against you in any way. As you read this form, and decide whether to participate, please ask all the questions you might have, take whatever time you need, and consult with others as you wish.

What is the purpose of the study?

The research is being done to gain further knowledge of how stress can affect heart rate variability when it is induced by different genres of music. The research is also being done to fulfill the requirements of SYSC 4201: Ethics, Research Methods and Standards for Biomedical Engineering.

What will I be asked to do?

If you agree to take part in the study, we will ask you to:

- Schedule a meeting time for a lab session located at Carleton University.
- Collect data about how your heart beats by means of electrodes attached to your skin and connected to an ECG.
- Wear noise-cancelling headphones and listen to classical and rock music

Risks and Inconveniences

- There is a small risk of skin irritation from the electrode affixed to the skin.
- There is a very small risk of shock from the bio radio used.
- There is a very low probability of unexpected health changes from inducing stress on your body. If this were to happen, the Carleton University Student Emergency Response Team (CUSERT) will be called and you will have medical professionals to help you.
- Auditory irritation can occur due to the volume of the played music.
- There is a small risk of skin irritation from disinfectant on the headphones
- Possible psychological harm if any incidental finding is found.
- **There is a very unlikely possibility that incidental findings are found from the ECG wave looking abnormal. If the researcher suspect the ECG looks abnormal, the experiment will stop, you will be informed. The researcher is not a trained healthcare professional and thus cannot make any valid interpretation or assessment. In such circumstances, you can consult with a healthcare professional if you wish.**

Possible Benefits

You may not receive any direct benefit from your participation in this study. However, your participation may allow researchers to gain knowledge about how stressors can affect heart rate variability.

Compensation/Incentives

Candy will be provided at the end of the session after the data has been collected. If you choose to withdraw during the session the candy will still be provided. Bottles of water will also be provided during the session.

No waiver of your rights

By signing this form, you are not waiving any rights or releasing the researchers from any liability.

Withdrawing from the study

If you withdraw your consent during the course of the study, all information collected from you before your withdrawal will be discarded.
After the study, you may request that your data be removed from the study and deleted by notice given to the Principal Investigator (named above) up to 24 hours after the collection of data.

Confidentiality

Attributable information that links participant identity to subject codes will be destroyed once the withdrawal period is complete.
We will treat your personal information as confidential, although absolute privacy cannot be guaranteed. No information that discloses your identity will be released or published without your specific consent. Research records may be accessed by the Carleton University Research Ethics Board in order to ensure continuing ethics compliance.

All data will be kept confidential, unless release is required by law (e.g. child abuse, harm to self or others).
The results of this study may be published or presented at an academic conference or meeting, but the data will be presented so that it will not be possible to identify any participants.
You will be assigned a code [or pseudonym] so that your identity will not be directly associated with the data you have provided. All data, including coded information, will be kept in a password-protected [or encrypted] Google Drive only accessible by the researchers.
We will password protect any research data that we store or transfer.

Data Retention

After **April 30th, 2019**, your de-identified data will be destroyed.

New information during the study

In the event that any changes could affect your decision to continue participating in this study, you will be promptly informed.

Ethics review

This project was reviewed and cleared by the Carleton University Research Ethics Board B. If you have any ethical concerns with the study, please contact Dr. Bernadette Campbell, Chair, Carleton University Research Ethics Board (by phone at 613-520-2600 ext. 4085 or by email at ethics@carleton.ca).

Statement of consent – print and sign name

I voluntarily agree to participate in this study. ___Yes ___No

_____ _____

Signature of participant Date

Research team member who interacted with the subject

I have explained the study to the participant and answered any and all of their questions. The participant appeared to understand and agree. I provided a copy of the consent form to the participant for their reference.

_____ __ _____

Signature of researcher Date

EMAIL TO BE SENT IN RECRUITMENT

Students of Carleton University!!

My name is Kabir Sharan and I am currently enrolled in my third year of Biomedical Engineering. One course in my program is SYSC 4201, Ethics, Research Methods and Standards for Biomedical Engineering and a major component of the course is conducting research. My research team and I are conducting an experiment to see the relation between heart rate variability and induced psychological stress. This experiment will be supervised by Dr. Adrian Chan, a professor in the faculty of Engineering in the department of Systems and Computer Engineering.

We are asking for 10 male and 10 female participants aged 18 or up to be a part of our experiment! Our experiment will consist of listening to various music types while seated and attached to an ECG. Participants may not have any flu like symptoms as well as any known pre existing heart conditions and participants with any known hearing conditions may not participate. Participation is voluntary and participants can withdraw for upto 24 hours after their session. All data and information will be completely private. Participants will be compensated with candy.
This project was reviewed and cleared by the Carleton University Research Ethics Board B. If you have any ethical concerns with the study, please contact Dr. Bernadette Campbell, Chair, Carleton University Research Ethics Board (by phone at 613-520-2600 ext. 4085 or by email at ethics@carleton.ca).

If YOU are interested or have any more questions, please feel free to contact me or one of my team members listed below!!!

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