Submission Type: Initial Date: 1-23-2018

IRB #: IRB-FY17-18-906
Title: It's How You Read It: Vocal Inflection and Tone as Predictors of Reading Comprehension
Creation Date: 1-9-2018
Status: Unsubmitted
Principal Investigator: Amy Krenzer

Personnel

Applicant Status

*Please click one below. Student led studies must select **Student** as the Applicant Status.*

- Faculty
- ✓ Staff
- Adjunct
- Student

Applicant: Faculty or Staff or Adjunct Faculty

Please provide the Principal Investigator and the Primary Contact of this study/activity.

Principal Investigator

- *If you are the PI, your name should have already auto-filled.*
- *If another faculty or staff will be PI, delete your name and find the PI's name below.*

Primary Contact

- *This can be the same individual as the listed PI.*
- *Select another individual as your primary contact if that individual will be managing the IRB submission process on your behalf.*

Please note: If you cannot find a person in a people finder, please contact the IRB Office immediately.

Principal Investigator

Provide the name of the Principal Investigator of this study/activity. (For Student Submissions, include your Faculty Sponsor's name here. and list yourself below as "Primary Contact".)

Name: Amy Krenzer
Organization: Institutional Review Board
Address: 1 Normal Ave. , Montclair, NJ 07043-1624
Phone: 973-655-7583

Primary Contact

Provide the name of the Primary Contact of this study/activity.

Name: Hila Berger
Organization: Research Compliance
Address: 1 Normal Ave. , Montclair, NJ 07043-1624
Phone: 973-655-3022

Co-Principal Investigator(s)

Provide the name(s) of Co-Principal Investigator(s) of this study.

Name: Hila Berger
Organization: Research Compliance
Address: 1 Normal Ave. , Montclair, NJ 07043-1624
Phone: 973-655-3022

Key Research Team Member(s)

Provide the name(s) of other key Research Team Member(s) for this study. You will be able to include any non-MSU collaborators under the next question.

List and Roles of Research Team Members

Please list and describe the roles of each additional research team member. Please include all research team members (affiliated and non-affiliated with MSU). Human subjects training verification (i.e. CITI) will be required ***only*** for those non-affiliated with MSU. This documentation will be requested in the following question.

For example:
Susan Day - Student - Study Lead, all research areas
Bill Jones, External University collaborator - Recruiter and Data Collection
Eddie Smith - MSU Faculty- Consenting and Data Analysis

Amy Krenzer (PI): All aspects of research
Hila Berger (Co-PI): All aspects of research

Are all the research team members affiliated with MSU?

✓ Yes

No, some research team member(s) are not affiliated with MSU.

Note:

- Once you have completed your submission and included all required attachments, a **Complete Submission** option appears under **Routing** in the menu.
- After clicking **Complete Submission** in the study sidebar, you will be prompted to confirm or cancel. Confirming marks the submission as completed and send it to the PI for certification.
- If everything is correct, the PI should then **Certify** the submission. (A submission must be certified to move forward to review.)

For more detail on completing a submission click here.

Activity

What type of activity is this submission for?

✓ **Research Study**

Is this a multi-institutional study?

Yes

✓ No

Has this study been previously approved by MSU or another IRB?

Yes, by MSU's IRB.

Yes, by another IRB.

✓ No

Secondary Data Analysis of de-identified data sets (where no Research Team Members hold linking codes or access to identifiers.)

Activities Without a Plan to Conduct Research (Case Study, Phase1 Grant with no Human Subjects Research, or Quality Improvement project) requiring Human Subjects Research determination.

Assurances

CITI Training (Human Subjects Protections)

Have all MSU personnel on this study completed human subjects training through CITI?

- ✓ Yes
- No

Child Abuse and Neglect Reporting Requirements [NJ Statute 9:6-8:10]

This NJ Statute requires any person having reasonable cause to believe that a child has been subjected to child abuse or acts of child abuse shall report the same immediately to the Division of Youth and Family Services by telephone or otherwise.

For specific information on reporting please visit http://www.nj.gov/dcf/reporting/how/index.html.

Will the research team comply with this statute and any other relevant state statues on child abuse reporting?

- ✓ Yes
- No
- N/A

Additional Institutional Approval

Outside of the IRB review process, Institutional Approval may be required for research activities that involve obtaining information or opinions from cohorts comprised of MSU community members (students, faculty or staff).

PIs will be notified if their study has been sent for this added MSU approval.

Adverse Events

XII. Report of Injury, Adverse Events, and/or Unanticipated Problems

A. Injury or unanticipated problem involving risks to subjects or others Investigators must report to the IRB, within 3 days of its occurrence, any injury or unanticipated problem involving risks to subjects or others as a consequence of the research project. By definition, an adverse event is any injury, problem, or unfavorable occurrence experienced by human participants or others during conduct of research activities. Adverse events may or may not be caused by the research protocol. They are recognized as occurring in the same span of time with the research. An adverse event may be anticipated and thus listed in the risks section of your protocol. If it is not included in the risk section of your protocol, it would be considered unanticipated. Unanticipated Problems should have the following characteristics:

1. Must be unexpected in terms of nature, severity, or frequency.

2. Must be related or possibly related to the participation in research

3. May suggest that the research places subjects or other persons at a greater risk of harm then previously recognized Investigators should use their best judgment regarding the nature and degree of a reportable injury or unanticipated problem. In general, whether anticipated or not, anything serious enough to warrant medical or psychiatric intervention is reportable, as are verbal or written complaints of subjects in which they proclaim that participation presents substantial discomfort, risk, and/or endangerment beyond that explained to them, or as otherwise stated in the consent form.

For more information please read and review the complete adverse event reporting requirements or you may select the help button on the upper right hand corner of this box for further review.

Please click below to verify that the PI and the entire research team member will comply with these requirements.

- ✓ I verify that the PI and the entire research team will comply with these requirements.

Certificate of Confidentiality from NIH

Will the research team request a Certificate of Confidentiality from NIH?
Click here for more information on CoCs.

- Yes
- ✓ No

Study Information

Study Dates

Please enter the anticipated study dates. These can be estimates and are not binding.

Start Date

Please provide the date for when the study will begin.
01/24/2018

End Date

Please provide the date for when the study will end.
01/24/2019

Study Sites

Please check all sites where the study will take place.

✓ MSU Campus sites

Please provide building name(s) and location(s) where the study will take place on campus.

NURS 333

Off Campus sites

Online

Study being conducting via Skype or another telecommunications application software product.

Locations outside of the United States

Study Population

Please describe the characteristics of your participant population(s).
Enrolled MSU undergraduate students matriculated as freshmen (over the age of 18) seeking an undergraduate degree.

Vulnerable Populations

Please check the population(s) that will be recruited and targeted for this study. Check all that apply.

Under the age of 18 years

Students currently enrolled in classes offered by any research team members

Human fetuses/newborns

Cognitively disabled or impaired

Diminished capacity to give informed consent

Veterans
(Only check off is this is your targeted population. Do not check if some participants may be veterans.)

Elderly or aged

Terminally ill

Undocumented persons

SONA - MSU's Student Participant Pool

Persons who are under the authority of the research team
For example: employees, staff, patients, clients.

Persons who are institutionalized
For example, prisoners, persons in hospices, persons in hospitals, nursing homes, rehabilitation

centers, homeless shelters, holding centers for immigrants.

✓ None of the above applies to this study

Ages

Please check the age range of subjects that will be enrolled in this study. Check all that apply.

Birth to five years old

6 to 17 years old

✓ 18 years and older

Participant Enrollment

Projected total enrollment

Please enter the total number of subjects to be enrolled over the complete course of the study, at all study sites.
500

Will participants be screened to include or exclude based on:

Gender

Ethnicity/Race

✓ Not applicable

Study Aims and Rationale

Provide the background, specific aims, hypothesis and rationale of the study.
Paraverbal communication factors such as inflection and tone of voice have been shown to significantly influence a variety of interpersonal behaviors (Author 1, Year). The skill of augmenting inflection and tone of voice has long been utilized by teachers to facilitate student understanding by way of conveying exact or emphasized meaning of words and phrases (Author 2, Author 3, and Author 4, Year).

But can paraverbal communication factors predict intrapersonal behaviors, such as reading comprehension? That is, can unassisted students harness the advantages of paraverbal communication for their own benefit? The aim of this study is to investigate the roles vocal inflection and tone play on the comprehension of vocalized reading material. The implications of this research load onto course development for college student general education requirements in communication as well as for student success, retention, and tutoring centers in higher education.

Benign Behavioral Interventions (BBI)

If your research only involves the following interactions on adults, it may be classified as a benign behavioral intervention (BBI). This requires less stringent recruitment and consent processes.

Is your study's data collection limited to **ADULT** participants involved in:

1) verbal (oral) or written responses by the participant and/or
2) data entry by the participant and/or
3) observation of the participant, including audiovisual recordings

- ✓ YES
- NO

Additional Requirements for BBI determination

Please check off all the conditions that match those in your research study.

- ✓ Participants who are not a part of a protected population, i.e. prisoners, cognitively disabled, indigenous populations or other.
- ✓ Brief in Duration -Meaning the intervention lasts only a few minutes to a few hours. While it does not have to occur in a single session, the entire time for the intervention should occur on a single day and not exceed a few hours in its entirety.
- ✓ Harmless
- ✓ Painless and not physically invasive

If you have checked off ALL of the above four boxes, your research may be a BBI. For BBI research you may use a Prospective Agreement Form in place of your standard recruitment and consent requirements. Please visit our webpage http://www.montclair.edu/provost/institutional-rev... for more information.

Also feel free to reach out to the IRB Office for more detailed information.

Recruitment

Please provide a description of the processes that you will use to recruit participants.
We will invite freshmen students over 18 to participate via departmental email list-serve.

Recruitment materials - You can find Recruitment Templates on our Templates webpage.

Please check all that apply.

- Flyers or posters
- Letters
- ✓ Email

Email attachment

Recruitment-Materials-IRB-FY17-18-906.docx

Telephone

In-person plea

Internet or Social Media (Facebook, website ad, twitter, etc.)

SONA Posting

✓ Recruitment information is included in the Prospective Agreement (see Consent Section)

Other

Overall Methods and Research Plan

Please describe your overall research plan. Specifically include the following:

- Data collection methods
- Timeline

For an example, please see the help text by clicking on the question mark to the right of this box.

We intend to begin recruitment in late January 2018 and continue each academic semester until December 2018. Data from the intervention will be in the form of audio recordings and data from the written examination will be recorded online in survey format.

After participants indicate interest in research study, PC will communicate to make an appointment time that is convenient for the participant. Appointments for research study will take place in NURS 333.

At the beginning of the session, the participant will be provided with a prospective agreement form and she/he will be asked to read it carefully. Participants will then fill out Demographics and Screening Form online. Participants will be required to disclose CWID, age, matriculation status, ethnicity, and gender for eligibility verification and for data analysis. If at this time, the participant is found to not be over the age of 18 and/or is not a Montclair State University student matriculated as a freshman, the participant will be informed of their ineligibility for the study.

Eligible participants will be informed about the two parts of the session -- the audio recorded reading and the examination.

Participant will then be moved to NURS 333A to complete reading after initial set-up by PC. Participant will be informed to return to NURS 333 after completion of reading.

Participant will then complete examination in NURS 333.

About 500 recordings and examinations will be conducted.

Digital audio files will be transcribed and then deleted.

Benefits of this Study

Please check all that apply.

Direct benefits to the participants

✓ Benefits to your field of study

Please describe the direct benefits to your field of study

Data from this study will be used to analyze the mediating factors of vocalized reading on reading comprehension. By localizing the effect of vocalized reading, researchers would be better able to inform teachers and curriculum developers on best practices for attaining student understanding.

Other benefits

Dissemination of research findings

Do you have plans to present or publish your research findings to a larger audience (outside of your classroom or department)?

✓ Yes

No

Research Data Security and Storage

All research data (including paper and electronic) must be treated with the utmost respect and confidentiality. This means that the information you obtain during the course of the study will not be divulged to others without permission or in ways that are not consistent with the agreement(s) between the research team and the participants.

All research data must be maintained for at least three years after the project is closed out or the results published, whichever occurs last. You may be required to keep the data for a longer time if mandated by the funding agency, publishers, or changes in MSU IRB policy.

Examples of research data are (but not limited to) notebooks, printouts, computer disks, photographs, scans, images, videotapes, audiotapes, flash memory, and electrophysiologic recordings.

Other documents that you are required to keep are IRB consent documents and documentation of assent.

Research data may only be altered or destroyed before this period with written permission from the MSU IRB

Research Data

Describe how the research team will store the data to ensure and maintain privacy, security, and confidentiality during and after completion of the proposed project.

All survey data will be stored on university qualtrics account. Audio recording data will be uploaded onto password protected university-owned computer accessed only by PI, Co-PI, and PC.

Research Data Policy

Will the research team process the data in accordance with the policies of MSU?
More information on Data Security in Research

✓ Yes

Retention of Study Data

According to MSU's IRB policies, what is the amount of time you must safely keep all research data, prior to destroying?

✓ Minimum of 3 years

You are correct! Unless given special permission by the IRB due to risks of a research study, you must keep all documents for a minimum of 3 years after study closure.

Maximum of 2 years

Not more than 5 years and not less than 2 years

Data and Identifiable Information

Will the research team collect information about the participants that could be linked to them?

✓ Yes

Please select all that apply

Address

✓ Age

✓ Audio recording

Blog or social media entries

✓ CWID

Date of Birth

Driver's License Number

Email Address

✓ Ethnicity

✓ Gender

Income

Job Title

✓ Name

Picture

Signed Consent and/or assent

Social Security Number

Standardized Test Scores

Telephone number

✓ Text message content

Video recording

Other

No

Linking Data

Will the research team use a linking code with the data?

Yes

✓ No

Sharing Data

Will the research team share identifiers or linking codes with anyone outside the research team?

Yes

✓ No

Pre-existing Data

Will the research team acquire pre-existing data for this study?

Yes

✓ No

Future Use of Data

Does the PI or the research team want to use the data obtained in this study in future studies?

Yes

✓ No

Family Education Rights and Privacy (FERPA)

Will the PI and/or the research team comply with the privacy measures of FERPA? FERPA applies to research involving a student's school record(s).

Yes

✓ Not Applicable

Protection of Pupil Rights Amendment

Will the PI and/or the research team comply with the privacy measures of PPRA?

(The PPRA applies to the programs and activities of a State educational agency (SEA), local educational agency (LEA), or other recipient of funds under any program funded by the U.S. Department of Education.)

Yes

✓ Not Applicable

Health Information and Privacy Accountability Act (HIPAA)

Will the PI and/or the research team comply with the privacy measures of HIPAA?

HIPAA only applies to research involving active medical or health information. This does not include self-reported health information.

Yes

✓ Not applicable

Screening Tools

Are you using any screening instruments to select your participants?

Yes

✓ No

Informed Consent

Will you obtain informed consent?

✓ Yes

Check all that apply.

✓ Adults

Children

No

Adult Consent

Check any and all that apply.

✓ Adult Consent Form

Link to the MSU IRB Adult Consent Form Templates

Readability for consent documents must follow:

- General public - 6th to 8th grade reading ability
- College Students - 10th to 12 grade reading ability
- Professionals -12+ reading ability

Adult Consent Form (s)

Please attach your adult consent form(s)
prospective-agreement.doc

Online Consent

✓ Prospective Agreement for Exempt Studies

These agreements can be used for any study that fits into an Exempt Review category and are required for Benign Behavioral Interventions. For more information see our webpage http://www.montclair.edu/provost/institutional-rev... or contact the IRB office.
For Prospective Agreement Templates go to our webpage:
http://www.montclair.edu/provost/institutional-review-board/forms/agreementforms

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Prospective Agreement Form

Please attach your Prospective Agreement Form
prospective-agreement.doc

Requesting waiver or alteration of standard informed consent procedures

Consent form non-English speaking participants

Debriefing form (for use in deception studies only)

Cognitively impaired or differently abled population consent

Participant Interaction

Please select all that apply.

✓ Online surveys/questionnaires

Please describe number of surveys and length of time to complete.

The box below will expand to hold a list of surveys if necessary, for example:
Student Online Survey - 10 minutes to complete
Adult Online Survey - 25 minutes
Teacher Online Survey - 40 minutes
Demographics and Screening Form - 5 minutes

Please attach your online survey(s) here

Reading Comprehension Test.pdf
Screening and Demographics Form.docx

✓ In-person surveys/questionnaires

Please describe number of surveys or questionnaires and length of time to complete.

The box below will expand to hold a list of surveys if necessary, for example:
Student Paper Survey - 10 minutes to complete
Adult Paper Survey - 25 minutes
Teacher Paper Survey - 40 minutes
Reading Comprehension Test - 90 minutes

Please attach all surveys and questionnaires.

Reading Comprehension Test.pdf
Screening and Demographics Form.docx

Interviews

Field Notes

Focus Groups

✓ Photos, audio and or video recording

Please make sure to include specific permissions to record participants within your consent document(s).

Please check all that apply.

- Photography
- Video recording
- ✓ Audio recording

Other

Examples: blood draws, MRIs, EEGs, audiology testing, medical devices, genetic testing or physical manipulation.

Will you offer compensation to your participants?

Compensation may include gifts, gift cards, raffles, money, or providing other similar incentives.

- ✓ Yes

Compensation description

Please describe your compensation. If your study is funded, please explain how you will document compensation.

Subjects will receive $15 for participation. PC will document compensation.

- No

Will there be any financial cost to the participant enrolled in this study?

Costs might include travel to the study, parking, or other expenses that would not be incurred otherwise.

- Yes
- ✓ No

Research Procedures

Does your research involve any of the following. Please check all that apply.

- Induction of mental or emotional distress
- Induction of physical stress
- Materials/issues commonly regarded as socially unacceptable
- Information regarding sexual attitudes, preferences, or practices
- Information regarding the use of alcohol, drugs, or other addictive products
- Information pertaining to illegal conduct
- Information in a student's educational record [this does not include self reported grades or student status]
- Information pertaining to a person's psychological health or well-being
- Information recorded in a patient's medical record
- Procedures that may be regarded as an invasion of privacy
- Information that if released, could reasonably damage an individual's financial standing, employability, or reputation within the community
- Administration of drugs
- Other risks to participants

Funding

Is this study funded or are you seeking funding?

✓ Yes

No

Funding Details

Sponsor Name

Please provide the name of the sponsor.

MSU Separately Budgeted Research

Other Sponsor(s)

If your sponsor is not listed above please provide any sponsor names. If you do not know the names of funding agencies you will approach, just state that in the box below.

Status of Funding

Please click one below.

Awarded

Pending award

Please attach a copy of your proposal. We only need the narrative and do not need your budget or budget justification in this attachment.

✓ Considering applying for funding but no grant application written at this time.

Conflict of Interest (COI)

Do you or any investigator(s) participating in this study have a financial interest related to this research project?

Yes

✓ No

Additional Study Notes

Do you have any additional notes for the IRB Reviewer, that may be crucial to the review and were not covered in the application?

✓ Yes

Please include any additional notes to the Reviewer and/or IRB office that you find may be helpful with this review of your study.

While public reading or the performance of math problems in front of an audience of strangers may be used to provoke a stress response in some research, the subject in this example is alone in a quiet room and reading from a standard text. An unintended disclosure of the subject's responses could potentially be significantly embarrassing.

Please include any additional attachments below if you find that are relevant to this study.

No

COMPLETING YOUR SUBMISSION

- Once you have completed your submission and included all required attachments, a **Complete Submission** option appears under Routing in the menu. (Each section should show a green check mark.)
- After clicking **Complete Submission** in the study sidebar, you will be prompted to **confirm** or **cancel**. Confirming marks the submission as completed and sends it to the PI for certification.
- If everything is correct, the PI should then **Certify** the submission. (A submission must be certified to move forward to review.)

For more detail on completing a submission click here.

Attachments

Recruitment Material(s)

Attach any Recruitment Material(s)
Recruitment-Materials-IRB-FY17-18-906.docx

Screening Tool(s)

Attach all copies of screening tool(s).

Adult Consent(s) Form

Attach the Informed Consent Form for Adults or if applicable Parent/Guardian form(s).
prospective-agreement.doc

Assent Form(s)

Attach the Assent Form or Scripts for Children

Debriefing Form(s)

Attach any debriefing Forms

Survey, Questionnaire, or Interview (s)

Attach all copies of surveys, questionnaires, or interviews.
Reading Comprehension Test.pdf
Screening and Demographics Form.docx

Site Approval(s)

Attach any Site Approval(s)

Data Use Agreement(s)

Attach any Data Use Agreements

Translated Material(s)

Attach any translated recruitment, consent or instrument(s).

Grant Proposal

Please attach the sponsor notification that states the intention to award the study.

Outside IRB of Record

Please make sure all of the documents below have been uploaded.

Study Protocol

Attach the protocol for this study that was reviewed by the outside IRB.

Outside IRB Approval

Attach the IRB Approval from the outside IRB.