Submission Type: Initial Date: 1-26-2016

IRB #: IRB-FY15-16-118
Title: Mindfulness Practices in Early Childhood Education
Creation Date: 1-26-2016
Status: Unsubmitted
Principal Investigator: Ida PI

Personnel

Applicant Status

Please click one below.

X 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: Ida PI
Organization: Kinesiology
Address: 424 Cayuse Ave , Portland, OR 90210-0004
Phone: 503-297-9043

Primary Contact

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

Name: Ida PI
Organization: Kinesiology
Address: 424 Cayuse Ave , Portland, OR 90210-0004
Phone: 503-297-9043

Co-Principal Investigator(s)

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

Name: Frank Faculty
Organization: Anatomy
Address: 2525 SW 1st Ave Suite 201, Portland, OR 97201-4762
Phone: 503-297-9043

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 - Study Lead
Bill Jones, External University collaborator-Recruiter and Data Collection
Eddie Smith -Consenting and Data Analysis
Ida PI- Co-coordinating all aspects of this research Frank Faculty- data analysis

Are all the research team members affiliated with MSU?

X 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?

X Research Study

Is this a multi-institutional study?

Yes

X No

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

Yes, by MSU's IRB.

Yes, by another IRB.

X No

Activities Without a Plan to Conduct Research (Case Study, Secondary Data Analysis of publicly available data-sets, or Quality Improvement project) requiring Human Subjects Research determination.

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.
09/09/2015

End Date

Please provide the date for when the study will end.
01/01/2017

Study Sites

Please check all sites where the study will take place.

MSU Campus sites

Off Campus sites

X Online

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

Assurances

CITI Training

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

X 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?

X Yes

No

N/A

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.

X 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

X No

Study Design

Study Aims and Rationale

Provide the background, specific aims, hypothesis and rationale of the study.

To explore how yoga and other mindfulness practices (i.e., deep breathing, meditation, visualization) are used in early childhood classrooms. We hope to learn how teachers think about and use different strategies to
enhance learning for young children with and without disabilities.

Recruitment

Please provide a description of the processes that you will use to recruit participants.

We will contact people, organizations, and schools by phone and/or e-mail to describe the purpose of the study and determine if they would be willing to help identify New Jersey early childhood educators who may be interested in participating in a short survey. In addition, recruitment postings on Facebook and Twitter
will occur.

Recruitment materials

Please check all that apply.

Flyers or posters

Letters

X Email

Email attachment

email text.docx
telephone script.docx
internet posting.docx

X Telephone

Telephone script attachment

email text.docx
telephone script.docx
internet posting.docx

In-person plea

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

Internet or Social Media Attachment

email text.docx
telephone script.docx
internet posting.docx

SONA Posting

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.

All data will be collected online through MSU's Lime Survey.
Data will be analyzed using simple percentages by the Co-PI and Graduate Assistant.
All data downloaded from Lime Survey will be maintained in a password-protected computer. All data collected will have no personal identifiers.
Simple percentages will be calculated for the multiple choice survey questions.
Open-ended questions will be analyzed qualitatively by first coding all the data and then categorizing them
 into similar emerging themes. Themes can be condensed, eliminated or expanded during the data
analysis process. Member checks will ensure there is agreement and validity.

Benefits of this Study

Please check all that apply.

Direct benefits to the participants

X Benefits to your field of study

Please describe the direct benefits to your field of study

Participants contribute to a growing research base in this area that can hopefully inform their teaching practices for young children.

X Disseminate research findings

Please describe your plan to disseminate the research findings

We plan on posting articles and/or links on early childhood mindfulness or related areas on Dr. PI's MSU Faculty Profile Page.

Other benefits

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 data downloaded from MSU's "Lime Survey" will be secured in a password protected computer. All of the data collected will not have any personal identifiers. Materials will be kept for three years after study closure.

Research Data Policy

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

X 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?

X 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?

X Yes

Please select all that apply

Address

Age

Audio recording

Blog or social media entries

CWID

Date of Birth

Driver's License Number

X Email Address

Ethnicity

Gender

Income

Job Title

X 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

X No

Sharing Data

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

Yes

X No

Pre-existing Data

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

Yes

X No

Future Use of Data

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

X Yes

Please include this permission on your consent document(s). If you plan to use the participant contact information for recruitment in future studies you must request permission from the participant within the consent document(s).

Please explain how and where the data will be kept for future use. If you do not receive permission for future use from a participant please explain how data will be separated.

All data will be kept in a locked file cabinet in the PI's locked office. Only people who areapproved for working on this study will have access. Participants who select that they do notwish for their data to be used in future studies will be stripped from the original data set.

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

x 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

X 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

X Not applicable

Study Procedures

Screening Tools

Are you using any screening instruments to select your participants?

Yes

X No

Informed Consent

Will you obtain informed consent?

X Yes

Check all that apply.

X Adults

Children

No

Adult Consent

Check any and all that apply.

Adult Consent Form

X Online Consent

Link to the MSU IRB Online Consent Form Template

Online Consent Form

Please attach your online consent form
consent form.docx

X Requesting waiver or alteration of standard informed consent procedures

Please provide a justification statement

Describe either:

1) Why the informed consent document must be altered or waived for this research protocol

OR

2) Why the requirement to obtain a signature must be waived for this research protocol

Yes, this is an alteration of standard consent procedures, since we will not be obtainingphysical signatures. This research will be conducted through an on-line survey tool andresearchers will not have in-person interaction with participants and not being collecting anyidentifiable information.

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.

X 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
1 survey - 10 minutes

Please attach your online survey(s) here

survey.docx

In-person surveys/questionnaires

Interviews

Focus Groups

Photos, audio and or video 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

X 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

X 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

Study Population

Please describe the characteristics of your participant population(s).
Early childhood (birth through second grade) educators who teach in New Jersey and use contemplative or reflection practices in their classrooms. These practices are sometimes referred to as mindfulness practices. Estimated numbers by gender based on higher average of female educators for pre-K - 2nd grade.

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
- Pregnant
- Human fetuses/newborns
- Cognitively disabled or impaired
- Diminished capacity to give informed consent
- Veterans
- Elderly or aged
- Terminally ill
- Undocumented persons
- Students currently enrolled in classes offered by any research team members
- 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.

X 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

X 18 years and older

Participant Enrollment

Projected total enrollment

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

120

Will participants be screened to include or exclude based on:

Gender

Ethnicity/Race

X Not applicable

Is this study funded or are you seeking funding?

Yes

X No

Additional Notes

If you have any additional notes for the IRB Reviewer, that may be crucial to the review and were not covered in the application, please feel free to add them below.

Conflict of Interest (COI)

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

Yes

X No

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- 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)
email text.docx
telephone script.docx
internet posting.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).
consent form.docx

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.
survey.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.