**University of Oklahoma – Norman Campus**

**Institutional Review Board**

**Description of Study Protocol**

1. **Provide a description of the purpose of your study and** your research design. (**Examples**: A pre-test – post test 2 x 2 experiment, with a control group and an experimental group that will receive one intervention. A grounded theory exploration of a topic. A pre-test post-test evaluation of a new classroom teaching method. An online cross-sectional survey of students related to curriculum topic. An 8-week walking study with a control and 2 comparison groups receiving either a diet or exercise message intervention). Guidance: This description should be short and written for a lay reader not for someone in your field. Also, your response should be understandable without the reader having to refer to another study document. Do not cut and paste your thesis/dissertation research abstract.

{Type your response here}

1. If your study will be conducted internationally, involves the military, involves deception, or includes non-OU research personnel, you should address the following areas related to your proposed study:
2. deception – the debriefing process that will be used
3. international research – review and approval of the study by a local ethics council, in country research support, verification of the cultural appropriateness of all study intervention and testing procedures and study documents
4. research involving the military – the unit that will be responsible for providing IRR or research approval and completion of the applicable DoD research approval form(s)
5. non-OU research collaborators – provide a contact information, institution of employment, and a description of the specific research responsibilities of each collaborator

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1. **Describe** your participants (examples: 10 day care directors in Tulsa, 50 employees of ABC Company in Norman, 5 people between 18 and 45 who do weight resistance exercise at least two times a week). **Include** information for each type of participant. Guidance: Many studies gather data from different types of participants such as teachers and their students, employees and their supervisors, kids and their parents. Be sure to provide a description of all types of potential participants and the number of each.

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1. **Provide** the inclusion and exclusion criteria for selection for each type of participant. **Where** will you obtain the contact information for potential participants? Guidance: If the information is public, describe the source of the contact information. You may not ask an organization or other entity to provide contact information for potential participants without their (potential participants) consent to release this information. You may ask that institution to distribute recruiting material that includes the researcher’s contact information so that potential participants can contact the researcher directly if interested in participating. If you involve an institution or other entity in recruitment activities, upload a signed, site- support letter, on the organization’s letterhead, that confirms that the signor has reviewed your research design and is willing to assist you in participant recruitment. Please note that access to contact information as a component of your job function DOES NOT automatically mean that you have access to this information for research purposes. This permission must be provided by your employing organization.

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1. **Recruitment: Who** will approach potential participants? What information are potential participants given about the study? What safeguards are in place to minimize coercion? **If** the researcher(s) is also the participants’ supervisor/instructor, how will you assure that the identity of the research participants remains unknown to the researchers until after (1) the data have been gathered and are de-identified or (2) the class grades have been assigned? Guidance: If the participants are under the direct supervision of the researcher(s) (such as employees or students of the researcher(s)), someone other than the researcher must conduct all recruitment and identifiable data collection activities. Upload recruitment materials, such as verbal or written scripts, email messages, postings to websites, flyers, and/or letters. If you recruit participants who are not at OU, include this language: ***“The University of Oklahoma is an Equal Opportunity Institution.”*** For OU mass email – you must have the proper permission to use the email list and must include this language in your email message: ***“The OU IRB has approved the content of this advertisement but the investigator is responsible for securing authorization to distribute this message by mass email.”***

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1. **What identifying information will you collect? How** long will you retain participant contact/identifying information? **How** will you store this information during the study? **How** will you dispose of contact information when the study is completed or when you no longer need this information? Guidance: If you do not have permission to report the names of your participants, then it is advisable to assign pseudonyms or study numbers to each participant as soon as the data are collected to reduce the risk to participants if research files are accidentally released. Participants can give you permission to release their identities or to store identifiable research records in the Waiver of Elements of Confidentiality section of the informed consent documents.

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1. **Provide** a step-by-step description of each of the tasks that participants will be asked to perform during the study. Guidance: Tasks include the consent process, completion of data collection instruments and any intervention or de-briefing activities.

**For each study task**, list each task sequentially in the order participants will complete it; indicate the approximate time it will take to complete each task and the setting (such as, in a classroom, in the participants’ workplace, in a public place, at home). Guidance: If you have multiple kinds of participants (i.e., students and teachers, employees and executives, etc.), include separate entries for each kind of participant and each task.

**For each data collection instrument**, indicate the frequency of administration and the method of administration (i.e., face-to-face, telephone, mail, or via a website). Guidance: Upload a copy of each data collection instrument, including surveys, questionnaires, interview protocols, questions for focus groups, observation recording forms, etc.

**For face-to-face interviews and focus groups/group interviews**, describe other persons who are not participants who will be present and the activities of each of these persons. **What** steps will you take to ensure that the discussion is held confidential by all the participants after the focus group? Guidance: All non-participant attendees are considered key study personnel since they have access to identifiable data. If someone other than the researcher will transcribe interviews, a confidentiality agreement should be completed and submitted with your application. A copy of the OU-NC approved confidentiality agreement form should be modified for your study and uploaded with other study documents.

**Task Time Setting Method of Administration**

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1. **What** steps will you take to protect the identity of your participants? If interviews or focus groups are audio recorded and will be transcribed, who will transcribe the audio, and how will participants’ identities be protected in the transcripts? Guidance: for audio-recorded data, you can mask the identity of the participants by using software programs such as Audacity (a free download). Also, participants should be addressed by a pseudonym or code during interviews to avoid inclusion of names that make interviewees identifiable or a procedure for de-identifying transcripts must be proposed. Photographs of classrooms should not include any identifiable images of the students under 18 who are in the classroom. If you intend to publicly release audio, video or photography, then you will need to have participants sign the OU Talent Release document.

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1. **How** will you store, secure, and dispose of each kind of data in your research records, including paper documents, electronic files, audio/video recorded data, photography and/or research records? **How** will you store and dispose of signed consent documents and master lists that link identifying information to ID code numbers? **For** what length of time will you retain your research records? Guidance: To retain research records that contain identifiable information about the participants (or that contain sufficient information for deductive re-identification) after the close of the study, you will need to provide a justification for this request. In addition, you will need to include the Waiver of Elements of Confidentiality section on the consent documents. For de-identified data sets with no potential for deductive re-identification of participants, research records can be kept indefinitely.

**Data type Storage Security Disposal Method Retention Time**

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