EAST TENNESSEE STATE UNIVERSITY

View xForm - New Protocol Submission V6

ETSU or MSHA researchers, submit this form for a NEW protocol submission. NEW: page jumping capability! Use drop down menu at top of page to move around within the xform!

New Protocol Data Entry
- Submitted 3/15/2016 5:25:45 PM ET by Garrett, Michael

1. Submitter Information

Submitted by

Garrett, Michael

Email:	zmdg11@goldmail.etsu.edu	**Mobile:**	423-737-7899

Enter your Project Title.

Seeing the World Differently. Professional Development Bridging Science and Lay Cultures

If funded or submitted for funding, the title must match your grant application.
VA Proposals must not exceed 142 characters.

Enter the email address of the Principal Investigator (PI).

Garrett, Michael

Email:	zmdg11@goldmail.etsu.edu	**Mobile:**	423-737-7899

If you are the PI, enter your own email address.
If you are not the PI, enter the PI's email address.
If you are not certain of the email address, save the form for later, obtain the email address, and return to the form to complete.

Please choose the most appropriate category describing the affiliation of the PI to ETSU.

ETSU student

--Subpage Student Information

Please choose the correct category for the student PI.

graduate student

Select the appropriate category of your research.

Doctoral dissertation

If you chose "other" above, please explain.

No answer provided.

Enter your estimated graduation date.

12/7/2016

Enter the email address of your Thesis or Dissertation Chair or Advisor.

Broderick, Jane Tingle Ph.D.

Email:	broderic@etsu.edu	**Phone:**	

2. Adequacy of Resources

Is there access to a population that will allow recruitment of the number of participants required to complete the study within the proposed recruitment period?

Entered: 02/05/16 **By:** Garrett, Michael

In process of negotiation

I am negotiating with the Kingsport City Schools to recruit K-3 teachers through their school system.

Please explain; do not just answer "yes".

Is there sufficient time to conduct and complete the research within the agreed research period?

Yes. It is feasible to recruit participants and do the half-day workshop before this summer.

Please provide explanation.

Are there adequate numbers of qualified staff for the foreseen duration of the research?

Yes. I am using fellow graduate students for staff.

Please provide explanation.

Are there adequate facilities for the foreseen duration of the research?

Yes. I can choose from 5 suitable rooms in Warf-Pickel

Please provide explanation.

Is there a process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions?

Yes. PI will train staff on functions and on privacy/confidentiality. PI will develop coding manual for video coders.

Please provide an explanation.

Is there availability of medical or psychological resources that participants might require as a consequence of the research?

No medical or psychological resources should be needed.

Please provide an explanation.

If the study is subject to HIPAA regulations, are the communication, data storage and data transfer vehicles HIPAA compliant?

No answer provided.

If your study is not subject to HIPAA regulations, you may skip this question.

If your study uses any of the following information that is created as part of health care, collected as part of health care, added to the hospital or clinical medical record, derived or extracted from the medical record, or used to make individual health care decisions, your study is subject to HIPAA. You must provide an answer with an explanation if your study is subject to HIPAA.*

**Names, Social Security Numbers, Device identifiers, Dates, Medical record number, Web URLs, Postal addresses, Health plan numbers, IP address numbers, Phone numbers, Account numbers, Biometric identifiers, Fax numbers, License/Certificate numbers, Photos and comparable images, Email addresses, Vehicle id numbers, Any other unique identifier*

3. Study Details

Please choose which method(s) this study includes.
You may choose more than one.

Entered: 02/16/16 **By:** Stoss, Yasmin

Please add educational intervention and survey as research methods.

Entered: 02/18/16 **By:** Garrett, Michael

I believe these are now included

educational intervention
Observational Study
Survey

If your study involves deception, be sure that deception study is selected in this box.

Is this a VA (Veterans Affairs) study (any research conducted at VA facilities, or using VA patients, time or equipment)?

No

If this is a VA study, you will need to complete your submission in paper and will not be able to continue this form.

Is this a MSHA (Mountain States Health Alliance) study?

No

Mountain States Health Alliance (MSHA) Research:
- If you utilize any of the MSHA facilities (hospitals) during a conduct of your research study
- If research is conducted by or under the direction of any employee of MSHA in connection with her/his organizational responsibilities
- If you are requesting a completion of a service from any of the MSHA departments (ex: MRI from radiology or laboratory service)
- If you are an investigator requesting access to MSHA medical records or other non-public information maintained by MSHA for collection of data and/or identification of potential participants
MSHA administrative approval is required in addition to IRB approval for any research conducted at MSHA facilities or using MSHA patients, time or equipment.

If you have questions about whether your study is a MSHA study, please contact the MSHA Department of Research at 423-431-5654.

Are you conducting the research at any sites outside of ETSU, MSHA or the VA?

No

Is this study sponsored currently or is it pending funding?

No

Will this research be conducted outside of the United States?

No

Does this research involve community based participatory research?

No

Community Based Participatory Research: "a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based participatory research begins with a research topic of importance to the community and has the aim of combining knowledge with action and achieving social change." (source: W.K. Kellog Foundation, 2001)

4. Study Staff Non-MSHA study (1 of 1)

Please enter the first and last name, email address, and choose the role for *each* study staff member.
To add another study staff member simply click the Repeat button at the bottom of the page.
When all staff are entered, click Next to proceed with your application.

Entered: 02/10/16 **By:** Garrett, Michael

I am locating study staff and will submit a Modification Request Form if I come up with staff after the Protocoll is approved

Entered: 02/16/16 **By:** Stoss, Yasmin

Please add your advisor here and we can wait for the modification later to add additional study staff.

Enter first and last name.

Jane Broderick

Enter email address.

broderic@etsu.edu

Please select the appropriate role.

Faculty Advisor

Will this person be the Primary contact for the role you've chosen?

Yes

*Please note: only **one** person can be the primary contact for each role. And, you must choose one primary contact for each role.*

6. Review Details

What type of review are you requesting?

Expedited Review (minimal risk as determined by federal guidelines)	*Assess the risk level of your study.* *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.* *If, in your opinion, your study is more than minimal risk, choose "Full" review.* *If you think your study is minimal risk or less, and is eligible for expedited review process, choose "expedited" review.* *If you think your study is eligible for exempt status, choose "exempt".* *The IRB will make the final determination.*

7. Applicability of HIPAA

Please answer these questions to assist in determining if the HIPAA regulations apply to your study. Please check any boxes that apply.

Is any of the following information* being:

none of the above/study does not use PHI	**Names, Social Security Numbers, Device identifiers, Dates, Medical record number, Web URLs, Postal addresses, Health plan numbers, IP address numbers, Phone numbers, Account numbers, Biometric identifiers, Fax numbers, License/Certificate numbers, Photos and comparable images, Email addresses, Vehicle id numbers, Any other unique identifier*

8. FDA and Radioactive

Does your study involve a drug, a medical device, or any data to be reported to the FDA?

No, none of these 3

Does the study involve radioactive materials?

No

10. Multi Site Study

Is this a multi-site study?

No	*A multi-site study is one where different PIs at different institutions are conducting the same study.* *Example of a multi-site study: a multi site clinical trial or a project performed jointly with another institution.* *Example of a study that is NOT multi-site: a single PI conducting a study at two different schools*

11. Study Objectives & Summary

What are the objectives of this study?

This study examines a core component of a successful professional development intervention introducing early childhood teachers to scientific modeling work and seeks to explore its promise to help elementary teachers teach science by improving the subjective value of science tasks and teachers' beliefs that they will be successful in science tasks.

The specific objectives of this study are to implement the target intervention in a controlled way to:

(a) assess whether it elicits prototypical scientific modeling behaviors from early childhood teachers;
(b) evaluate whether early childhood teachers value this kind of work as enjoyable and useful;
(c) measure the intervention's effect on teachers' beliefs about their abilities to succeed in science related tasks such as teaching science and learning science;
(d) evaluate this intervention as socially valid professional development.

Describe the purpose(s) of the study. Why are you conducting the research?

Example of a detailed response:
The objectives of this study are:
a. To determine whether providing detailed completion instructions in a clickable format within IRB submission documents will improve the completeness of IRB submission packets
b. To determine whether the addition of detailed instructions in IRB submission documents improves researcher satisfaction with the submission process
c. To determine whether the addition of detailed instructions in IRB submission documents reduces the time from submission to approval of the project

Example of an inadequate response:
To see if adding instructions helps

Why is the IRB asking this question?
In order to ensure ethical research, the IRB must determine whether there is a balance between risks, benefits, and the importance of the knowledge that may be expected to result from your study. Clearly and specifically stating the objectives of your project begins to provide information about knowledge you may learn from this project.

Summarize the study.

Entered: 02/12/16 **By:** Stoss, Yasmin

will you collect and analyze the journals and any other documents the teachers create in this workshop?

Entered: 02/12/16 **By:** Stoss, Yasmin

Is the educational intervention (workshop) part of the research? In other words, would you be conducting the workshop even if you weren't doing this research project?

Provide a brief but thorough description of the study. What is the study about? This does not need to contain a summary of background literature. It should just summarize the study itself.

In this study, the researcher will organize an educational intervention to deliver in a controlled way a core component of a successful professional development course, _Seeing the World Differently_. The intervention comprises a half-day workshop offered to a volunteer sample of early childhood teachers recruited from a local school system. The intervention is part of the research study and is not offered currently outside the study.

Dependent variables of interest are teacher modeling behaviors, teacher attitude towards science related tasks, and teacher overall evaluation of the workshop. The workshop as a whole is considered a treatment; however, data will allow assessment of participants' evaluation of individual workshop components.

The workshop uses small-group and whole-group activities that give participants opportunities to engage in prototypical scientific modeling tasks in a culturally sensitive contexts simulating some of the imperatives of science work. Participants will work in small groups to manipulate physical setups (ketchup in a bottle, a toy car, a ball in a wagon) and to describe and explain what they see in pencil-and-paper representations. The workshop facilitator will interact with the groups in small intrude-and-withdraw engagements to emphasize consistency, coherence, and clarity in their representations. Teachers will discuss their group work in a plenary session and then make one final attempt to represent their thinking on paper. In a final debriefing session, the facilitator will present a canonical description and explanation of the phenomena and will lead a discussion in which teachers compare these to their own work.

During the study, each participant will be asked to:

1. fill out an online demographics questionnaire.
2. fill out an online survey about their attitude toward teaching science (the STEBI).
3. keep a structured journal during the workshop to record their experiences with workshop components.
4. contribute to pencil/paper booklets (Flipbooks) describing and explaining the phenomenon in the physical setups.
5. fill out a pen/paper workshop evaluation questionnaire at the end of the workshop.

Besides the survey data, the journals and flipbooks will be collected. The journals contain short questionnaires on participants' reaction to workshop components and allow open-ended responses. These will be analyzed for the interest and utility value of the components. Flipbooks will be analyzed informally for a sense of the engagement with the modeling tasks and saved for possible later analysis of modeling techniques. In

addition, workshop activities will be video recorded to be coded for target modeling behaviors.

Participants will be given a random ID prior to any data collection. All data will be keyed to this ID. Online demographic and attitude data will be collected using the survey platform, Typform. Typeform is a professional survey collection tool that enables individual account owners to design complex, interactive data collection forms and to download the results via secure servers. Typeform does not collect IP information or other identifiable information from respondents. The researcher will set up a password-protected account for this study.

The final component of the workshop offers a debriefing period for participants to express their reactions verbally and on paper. All participants will be offered paper and digital templates for the Flipbook materials and descriptions of the physical setups for use in their own classrooms. All participants will be encouraged to follow-up with the researcher via email.

12. Recruitment & Enrollment

Identify the participants. Check all that apply.

Adults over the age of 18
Healthy volunteers

If you selected "other" above, please specify what other participant population you will be studying.

No answer provided.

Does the list of participants for this study include vulnerable populations?

No

This question requires you to consider the populations that might be enrolled in your study. Are there any populations that are vulnerable and will require extra protections? Populations that are likely to be vulnerable to coercion or undue influence include populations with asterisk above. In addition, other populations may be considered vulnerable persons.

If you answered "yes" to the question above, describe the additional safeguards included in this study to protect the rights and welfare of the participants.
Skip this question if you answered "no".

No answer provided.

This question asks how you as the PI will build in extra safeguards to make sure that you protect the rights and welfare of vulnerable populations.

Example of a thorough response:
This study will involve analysis of maternal-child interaction immediately after delivery. This study incorporates the following additional safeguards:
1. A packet of information about this study will be provided to prospective participants during a routine obstetrical doctor visit rather than at presentation in labor. This will ensure that the mother has ample time to consider whether she wants to participate in this study and is not making this decision under the duress of labor. Mothers will be encouraged to take the packet of information home and discuss the study with their family. They may enroll in the study at any of their subsequent routine doctor visits. Mothers in active labor will not be approached for enrollment in this study.
2. The consent process/enrollment will be conducted by a member of the study staff who is not actively involved in the medical care of the patient. This will help ensure that participants clearly understand that choosing not to participate will not have any impact on their normal medical care.
3. Refer to Additional Section on Pregnant Participants for additional information.

Example of an incomplete response:
Consent will be obtained.

Why is the IRB asking for this information?
In order to ensure that the ethical standards from the Belmont Report are upheld, the IRB must determine that there are appropriate safeguards in your study to protect the rights and welfare of vulnerable participants. Your study can not be approved unless the safeguards are determined to be present and appropriate.

--12B. Recruitment & Enrollment - Page 2

Describe how the selection of participants is equitable in relation to the purpose of the research and the setting in which the research will be conducted.

The purpose of this study is to better understand the components of a professional development workshop intended to improve elementary science teachers attitudes and motivation around science and science teaching. Participants will be recruited through a professional development offering by the Kingsport City Schools. Any elementary school teacher in that system may apply. The burden of participation is no more than any other professional development workshop and the benefits are in line with such workshops.

This question requires evaluation of 3 considerations and their relationship.
1. Selection of participants (which groups are you selecting to be in your study?)
2. The purpose of the research (from the question about objectives)
3. The setting in which the research will be conducted

Points to consider:
1. Does the nature of your research require using the population you have proposed?
2. Are there any groups of people who might be at more risk in this research and who should not be included? If so, be sure to detail how you will identify those who should not be included.
3. Would it be possible to conduct your study with participants who are less vulnerable?
4. Are any potential benefits or burdens distributed fairly?
5. Are you excluding participants of certain gender, age, ethic groups, etc, and if so, what is the scientific basis for the exclusion? Ex: conducting a survey of only 2nd grade boys, explain why other grades and girls will be excluded

Example of a thorough response:
The purpose of this research study is to examine the safety and efficacy of investigational drug X for heart failure. As the drug has previously been evaluated in Phase I trials in healthy volunteers, it is now necessary to evaluate efficacy in populations with the target disease of congestive heart failure. As drug X is known to affect kidney function, participants whose kidney functions tests are below normal will be excluded to minimize risks to this group. As noted in the procedure section of the narrative, BUN and creatinine will be drawn at baseline and any participant whose values for both tests are outside of the normal reference range will not be enrolled.
Flyers will be placed in the physician offices of all investigators in this study for recruitment purposes and any patient who expresses a desire to participate and meets the inclusion/exclusion criteria is eligible for enrollment.

Example of an incomplete response:
Selection is based on inclusion criteria.

Why is the IRB asking this question?
In order to uphold the principles underlying ethical research, the selection of subjects must be equitable. This helps ensure that the benefits and burdens of research are distributed fairly.

Describe the specific steps used to identify and/or contact prospective participants.

Entered: 02/16/16 **By:** Stoss, Yasmin

1) Please provide a copy of the letter or flyer that will be used and attach it in section 24.
2) Please detail how the invitation will be presented (i.e. flyer, email, etc.).
3) Would school administration be providing recommendations of teachers to participate or presenting an open invitation?

Entered: 02/17/16 **By:** Garrett, Michael

This is in negotiation still, but I believe this is how it will be done.

This is in negotiation with district administration. Possibilities include: District administration may circulate an open invitation to district K-4 teachers through the districts internal mail system, or they may include it as an offering in their professional development schedule.

Include who will make the initial contact and how the contact will be made.

If applicable, describe how you have access to lists of potential participants.

District administration will provide a list of prospects. The participants will be selected from this pool.

--12C. Recruitment & Enrollment - Page 3

Will you be using letters, scripts, or advertisements?

Yes

This includes letters that will be sent to anyone who is to be considered to be a potential participant in the study, scripts of any kind, and advertisements used to advertise the research to potential participants.
Provide a copy of any material with this application. In addition, the IRB must review and approve final copies of all audio and videotapes prior to use. If an advertisement is to be broadcast, the IRB may review and approve the wording prior to taping. The approval of the final taped message prepared from the IRB-approved text can be given through expedited review.

List the criteria for inclusion and exclusion.

Inclusion: Practicing teachers of elementary-aged children, generally teachers of grades K-4.

Exclusion: Non-English speakers

If you prefer to attach a copy of the inclusion/exclusion criteria rather than enter here, see next question. Include populations that will be excluded and included in the research.
Example: Exclusion: Minors under the age of 18, Inclusion: Adults over the age of 18

Attach a copy of the inclusion/exclusion criteria here if you did not enter the information above.

No answer provided.

Explain the procedures that will be used to determine eligibility.

Volunteers will be asked to identify themselves as elementary teachers within the Kingsport City School system. If they self-identify as non-English speaking, they will be ineligible.

How will you determine who is eligible to participate in the study? How will you know who can participate in the study?

How many participants do you *plan* to enroll in this study?

12

13. Consent of Non-English Speaking Participants

Will non-English speaking participants be consented?

No

14. Waiver Request

Are you requesting a Waiver?
Please choose the appropriate response based on the criteria listed.

No Waiver(s) requested	*Your request for a waiver does not guarantee you will be granted the waiver because the IRB makes the final determination.*

15. Consent by LAR

Are you requesting permission for consent by legally authorized representative?

No	*This question is asking if you are proposing to obtain permission from the legally authorized representative of the participants you are enrolling. If "yes', the IRB must approve enrollment of participants based on the permission of a legally authorized representative LAR before enrollment of participants using LAR can begin.*

If yes, what is the rationale for this request?

No answer provided.

16. Informed Consent Process

Who will be obtaining informed consent?

Michael Garrett	*This question is asking which members of the study staff will be going through the consent process with the participants. If a waiver is being requested, state that here.* *Note: Persons involved in the consent process must be members of study staff and must have completed IRB education requirements.*

Does the person obtaining consent have an existing relationship with any of the participants?

No

If yes to the previous question, describe that relationship and how you will protect against undue influence or coercion.

No answer provided.	*This can include but is not limited to: physician/patient, teacher/student, coach/athlete, lawyer/defendant, etc. This is to make sure undue influence or coercion are not present.*

Describe the timing of the consent process, and any waiting period between discussion and consent.

Entered: 02/12/16 **By:** Stoss, Yasmin

will you expect them to sign and email the consent form back to you or will you provide fresh copies for signing at the workshop?

Entered: 02/17/16 **By:** Garrett, Michael

I will need informed consent prior to online data collection, which will start before the actual workshop. Is there a digital way I can get a signature? Is a scan or a photo of a hand-signed form sufficient?

Entered: 02/18/16 **By:** Stoss, Yasmin

emailed the PI to set up a meeting to discuss possible solutions.

Informed consent will be collected in two stages:

1. The landing pages for the online survey will present teachers with an informed consent statement for the survey and a chance to opt out of the survey.

2. All participants who complete the online survey will receive via email a copy of a second informed consent statement for the workshop at least one week prior to the workshop. If they consent, they will sign this and bring it to the workshop. Copies will be available at the workshop as well, and any participant who has not brought a signed copy will be given a copy and ask to read it in private and decide then to proceed with the study.

Explain the timing between the time you discuss the study with the participant and the time they make their decision to participate or not participate.
The participants should be given sufficient time to make a decision on whether they want to participate or not. The participants should never feel coerced to participate because of lack of time in the process. However, there are times when situations warrant that a decision be made quickly. Ex: heart attack study

Are there any anticipated circumstances under which the participant will be removed from the research by the investigator without the participant's consent?

No

Do you anticipate removing the participant for any reason without their consent?
Note: The participants must be notified about the possibility of them being removed from the study for any reason by adding this information to the letter to participants or the informed consent document that will be given to participants.

If you answered yes to the previous question, list those circumstances.

No answer provided.

Examples: no longer in the best interest of the participant; fails to follow protocol, etc.

17. Specific Role of & Risk to Participants

Describe what the participants are expected to do once enrolled in the study.

Complete two online questionnaires, attend a half-day workshop which will be video recorded, maintain a journal of experiences during the workshop, complete a final online questionnaire at the end of the workshop

Examples: complete a survey/questionnaire, attend an interview, attend a conference/workshop, etc.

Describe any risks to participants if they are enrolled in the research.

Entered: 02/16/16 **By:** Stoss, Yasmin

The participants will be videotaped. Please add the potential loss of confidentiality as a potential risk.

Participants will be video recorded during the workshop. This presents a risk of loss of confidentiality. Besides this, there are no risks to participating in this study outside of what they may encounter in normal life and professional development.

Be sure to consider physical, psychological, economical, social and legal risks.
If there are no foreseeable risks, then state so. Do not indicate NA.

18. Minimizing Risks to Participants

How does this study use procedures which are consistent with sound research design and which do not unnecessarily expose participants to risks?

This study is designed to find whether teachers who are not expert in physics show behavior consistent with current understanding of scientific modeling under workshop conditions and whether the participants value and enjoy the components of the workshop. The materials and situations are typical of daily life or of standard professional development and involve no risk greater than what the participants would find in their normal life and work.

This is an exploratory study and does not seek to establish correlations or cause and effect. Therefore, a small sample of volunteers is adequate. Demographic questions ask for participant information typical of studies on teacher attitudes and practices (gender, grade level taught, years teaching, etc.). Attitude questions are consistent with the literature around motivation for achievement behaviors (do you find it interesting, enjoyable, etc., describe what you found interesting, enjoyable, etc.). Video recording of workshop activities are necessary to answer questions about participants modeling behavior. Video data will be handled in accordance with stipulations in the informed consent agreement and with general procedures for maintaining confidentiality of data that might identify participants.

Data on participants is not particularly sensitive: standard demographic data, opinions about science and workshop components, and video recordings of behavior typical of classroom or professional development work. Nonetheless, all personal responses will be kept anonymous by keying them to a random ID given to the participants at the beginning of the study. Correspondence between ID and names will be kept private to the PI only. Video data recordings of participants will be kept secure by the PI and not be shared outside of the study personnel without editing out any identifiable personal information. PI will train video coders on maintaining privacy. Coders will be blind to the full names of the participants.

For a study to meet ethical standards, risks must be minimized. The regulations note two specific methods by which this may be accomplished. This question requires information about one method (see next question about the second method).
Points to consider:
1. Have you considered physical risks, psychological risks, economical risks, and social and legal risks?
2. Can alternative or fewer procedures answer the scientific question and reduce the likelihood or magnitude of harm?
3. Have you built in adequate safeguards into your research design? For example, does your proposed study require frequent monitoring, coding of data for confidentiality, or the presence of trained personnel for procedures?
4. If your study involves a blinded design (investigator and/or participant don't know which treatment a participant is receiving), is there a mechanism to break the blind if necessary?
5. Are there risks that cannot be avoided? If so, how can you reduce or mange those risks? Are there precautions, safeguards or alternatives that can be built into the study design?
6. Have you provided information about the competence of the investigators/ study staff? (for example, if the study requires a blood draw, discuss the qualifications of the study staff member who will be performing this task.
7. Have you demonstrated how your study is designed to yield useful data?
8. Have you provided complete information to the IRB regarding the scientific rationale supporting your proposed research?
9. Have you provided information about the statistical basis for your design/sample size?

Example of complete response:
As drug X in this study is known to affect kidney function, blood draws to assess kidney function will be collected weekly. The study coordinator, a certified medical technician, will collect the blood samples. The PI will review the lab results within 24 hours of collection and will immediately withdraw the participant per protocol if values are outside the normal reference range.

The use of a double-blind design in this study will control for undue bias on the part of the research team. Sealed envelopes containing the code are stored in a locked cabinet in the PI's office. All investigators have been trained on the procedures should an individual's treatment group need to be determined.

The sample size for this protocol was determined on the basis of a power analysis conducted by a statistican.

Example of an incomplete response:
This double-blind study will be conducted in the clinic.

Why is the IRB asking this question?
In order to uphold the principles underlying ethical research, risks must have been appropriately minimized.

Whenever appropriate, how does this study use procedures already being performed on the participant for diagnostic or treatment purposes?

There are no diagnostic or treatment procedures.

This question requires information about another method to reduce risks.
Points to consider:
1. Are procedures that can answer the scientific question being done anyway? If none are being done, state that.
2. If so, can the data from those procedures be used to reduce the likelihood or magnitude of harm?

Example of complete response:
If participants in this study have already had their cholesterol checked within the last month, then those results will be used for this research study rather than requiring additional blood draws.
In addition, if participants have had a chest x-ray within the last year, those results will be utilized rather than exposing participants to an additional x-ray.

Example of an incomplete response:
Some previous tests will be used.

Is the research more than minimal risk?

No

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Note: You can make the initial evaluation but the IRB makes the final determination of risk level.

Does the research involve an intervention?

Entered: 02/16/16 **By:** Stoss, Yasmin

You mentioned an educational intervention. Is the education part of the research activities? If the answer is yes, please change the response to the question below.

Yes

Intervention is defined as including both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. 38 CFR 16.102(f) notes that "an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes."

19. Benefits to Participants

Describe the benefits to participants.

I've used the methods in the workshop elsewhere with early-childhood teachers and with students. They typically say that it helped them understand science and gave them ideas for their classrooms, and that it made science and science teaching seem more approachable and enjoyable. Also participants will get reproducible materials they can use in their own classroom and access to an ongoing blog about how these methods work. Participants will have the opportunity for follow-up work with their peers and with me on how to integrate science work with mathematics, literacy, and social studies in their own classroom.

What are the potential benefits to participants or society as a whole if this study is conducted? Note: Do not include information about payment to participants or extra credit in this question.

Describe how the risks to participants are reasonable in relationship to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

There is a risk of loss of confidentiality due to the video recording of participant activity. This risk will be minimized by editing out identifying information (such as name and school affiliation) from any video data that is used publicly, and by keeping unedited data in secure and password-protected storage. Besides this, the study imposes no risk to participants above their normal life and work.

There are, however, potential benefits to the larger community of elementary teachers and their students, specifically in motivating science-averse teachers to attempt academic science tasks and in developing scientific modeling practices in elementary school.

Research has shown that many elementary school teachers are worried about trying to teach and learn science based on their past experiences with science subjects, especially with physics, and that they tend to avoid science subjects in their classroom and avoid learning more about science themselves (van Aalderen-Smeets, 2015). It has also shown that this can reduce what their students learn about science and can pass on negative attitudes to them. Improving teacher and teacher candidate attitudes about science tasks has proven to be tractable, but definite methods are not well-developed (Thomson, 2013).

Compounding this difficulty, current national trends in K-12 science education ask teachers to change their teaching practices to bring more work prototypical of actual science work into their classes (NGSS, 2013), work that elementary teachers in particular are unfamiliar with and averse to (Chalfufour, 2010). Of particular interest in these standards and in the Common Core Math standards, is the practice of scientific modeling (NRC, 2011). It is, however, proving difficult to move established teachers to make the change in classroom practices necessary to bring such work into science classes (Barthelomew, 2004). Further, elementary teachers in particular are reluctant to engage professional development around science teaching.

There is considerable research, however, linking personal interest value and utility value of academic tasks to individual's motivation to attempt such tasks in achievement environments, especially with women (Eccles, 2007). Most of the work around this gendered resistance to academic science has evolved around how cultural messages of personal cost and attribution of success demote the subjective task value and the expectation for success of academic science tasks. There is little research, though, on how personal interest and utility can be enhanced to promote this subjective task value, even though there is indirect evidence that both of these can be powerful drivers of engagement with actual science work in both adults (Giere, 1990) and children (Lee, 2002). In addition, when teachers understand science practices, such as modeling, and are positive about them, a developmentally appropriate pedagogy is possible (Lehrer, 2010).

By understanding better what parts of the

In order for a study to meet ethical guidelines, risks to participants must be reasonable in relationship to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

Points to Consider:
1. In evaluating this information, the IRB will consider if the importance of the research aims is clear and if the research is likely to achieve its proposed aims. Physical, psychological, social, economic and legal risks must be considered.
2. The IRB must determine the following:
• The likelihood and magnitude of the risks and potential benefits, and understand the importance of the knowledge reasonably expected to result.
• the range of harm, including physical, social, economic, psychological, and legal harm.
• the range of benefit. Benefit can take the form of therapy, education, information, resources or empowerment. The benefits can be directed at participants or their community as a whole.
• The validity of research design must be taken into consideration in determining the risk benefit ratio
• What is the importance of the knowledge expected to result from the research?

intellectual work around prototypical scientific modeling tasks elementary school teachers find both interesting and useful, designers of professional development interventions targeting the averse attitudes of this population towards teaching and learning about science can better engage and motivate teachers. The professional development work under exploration in this study has anecdotal promise as a means of bringing early childhood teachers to both enjoy and value modeling tasks as a means of exploring the world and bringing science practices into their classrooms. However, this work needs to be explored in a controlled way to test whether this effect is at all robust, to rule out some competing explanations (such as attribution statements of the facilitator), and to develop refined materials, techniques, and metrics. In this way, participants of this study can contribute towards improving the state of elementary science education generally.

##References

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van Aalderen-Smeets, Sandra I. and van der Molen, Juliette H. (2015). _Improving Primary Teachers' Attitudes toward Science by Attitude-Focused Professional Development_

20. Payments & Costs to Participants

Are there any payments being offered to participants?

No

Will there be any additional costs to the participant that may result from participation in this research?

No

If yes to the previous question, describe those costs.

No answer provided.

21. Participant Privacy & Confidentiality

Please answer the following questions regarding participant privacy and confidentiality. You may need to scroll down the page to answer all questions.

Describe how the privacy of participants will be protected.

Participants will fill out online surveys at a time and place that they wish. During the workshop, they will be able to move around the work area or relocate outside the room to take paper surveys and journals if they wish. Workshop staff will be instructed to not ask participants about their responses and to move away from them during this time.

Privacy refers to the person rather than the data. Consider issues such as whether the participants will be comfortable in the research setting when completing a survey, questionnaire or being interviewed and whether the participants will think the information being sought is any of the investigator's business.
Examples:
- when participants are completing a paper survey or questionnaire or undergoing a physical exam, will the participants be in a private room? If not, how is their privacy maintained while completing the survey or questionnaire?
- When participants are completing online surveys or questionnaires, will they be completing them in a place of their choice?

Example of an incorrect response:
Data will be stored in locked cabinet (This addresses confidentiality, not privacy).

How will research data be recorded and maintained? What safeguards are in place to ensure confidentiality? (e.g., locking computer, logging off the computer after use, password protected computer access, locked office or storage cabinet)

Entered: 02/12/16 **By:** Stoss, Yasmin

if any of the surveys are done online please explain security measures such as the collection of IP addresses

Entered: 02/16/16 **By:** Stoss, Yasmin

You mention video coders and videographers. Are these other students or employees with company? Are they paid?

Entered: 02/18/16 **By:** Stoss, Yasmin

Please note that these video coders will need to be added as staff.

All survey and journal data will be identified by ID only. Name-ID correspondences will be kept on a password-protected hard drive or password-protected secure server. Paper backup copies of these correspondences will be kept in a locked cabinet in the PI's office.

Online surveys will be conducted via a professional survey platform (Typeform) which does not collect IP addresses or other identifying information from respondents.

Pencil-and-paper journals, questionnaire, and representations of thinking generated during the workshop will be identified by ID only.

Video will be downloaded from recording devices to password-protected hard drives or secured servers and deleted from the recording devices. Master copies of video data will be kept on a password-protected hard drive or password-protected secured server. Video clips used for coding will be kept on password-protected hard drives or password protected secure servers.

Video coders will be recruited from graduate students and faculty in education at ETSU. As they are recruited, video coders will be added to the IRB system as staff and will sign conflict-of-interest statements. Video coders will be trained by the researcher in the study security protocols. Video coders will have access to data only for the duration of their work on the video.

Are you recording identifiable information? How will you be maintaining the data collected during the course of the research?

Who will have access to the research information? Choose all the people who are appropriate.

Study Personnel
ETSU IRB (check if non-medical research)

Does the protocol involve the use of identifiable data?

Yes

Describe how the confidentiality of participants will be assured.
Include a description of any issues specific to the study that might increase the risk of loss of confidentiality.
If codes will be used to protect identities, describe how codes will be generated and who will have access to the codes.

Entered: 02/12/16 **By:** Stoss, Yasmin

You say that video files will be labelled by participant name. Will you tape them individually and in what context? Are you doing a video journal or interviewing them?

Participants will be assigned a random ID using an Excel spreadsheet. Individuals will be given this ID via private email from the PI when they join the study. Only the PI will have access to ID-name correspondence. Survey responses, teacher journals, and other physical artifacts will be identified by ID only. Online surveys will be collected via the Typeform survey collecting platform. Typeform does not collect IP addresses or other identifying information on respondents.

Video recordings of group activities during the workshops will not be labeled by participant name or other identifying information. Individuals will not be interviewed separately. Video recording is of participants working in small groups and in large plenary sessions. Any identifying information that may appear in the video data (such as personal names of school affiliation) will be edited out before clips are used in academic presentations or in teaching. Unedited video data will be secured and accessible to study personal only for the time they need to analyze data.

Will the data be electronically or physically sent to another location?

Entered: 02/16/16 **By:** Stoss, Yasmin

Please change this response to yes since you will be removing the data from the school site to the PI's office and downloading data from the surveys.

Yes

If yes to the previous question, describe the provisions for transporting the data securely.

Entered: 02/16/16 **By:** Stoss, Yasmin

Please answer this question.

Entered: 02/18/16 **By:** Stoss, Yasmin

please describe how you will transport the physical papers and video recorder in a secure fashion.

Entered: 03/07/16 **By:** Stoss, Yasmin

Please describe how paper data (journals and such collected during workshop) will be transported securely.

Online survey data will be downloaded via secure server to password-protected storage. Video recordings will be downloaded from recording devices to password-protected storage and deleted from the recording devices at the time of the workshop. All paper data (journals, representations of thinking, and questionnaires) will be collected by the researcher and kept in his possession until secured as soon as possible in locked storage in the PI's office in the Center of Excellence in Early Childhood Education at ETSU.

Where will records be stored for the required period?
5 years or longer as required by sponsor or FDA for non-VA studies. Indefinitely for VA studies?
(if appropriate, include institution, department, building and room number)

Entered: 02/16/16 **By:** Stoss, Yasmin

Please provide the exact location/address where the records/data will be stored.

Entered: 02/18/16 **By:** Stoss, Yasmin

please provide a building name and room number

Entered: 03/09/16 **By:** Stoss, Yasmin

PI has not answered this question

Paper data (participant journals, participant representations of physical phenomena) will be kept in locked storage in the PI's office in the Center of Excellence in Early Childhood Education at ETSU. Paper copies of survey data and name-ID correspondence will be kept in locked storage in the PI's office. Unedited master copies of video recordings of workshop activities will be kept on a password-protected hard drive in the PI's office.

Does the study include the use of audio or video taping?

Yes

-- Subpage Identifiable Data

Explain why it is necessary to the research to retain this identifying information.

The only identifiable data are the video recordings of workshop activities. These are essential for coding targeted modeling behaviors.

If the research requires that you retain identifiable information (information that can possibly identify who the participants are), then an explanation must be given as to why this is important to the research.

Describe the provisions to destroy the identifiable data once it is no longer needed. Include provisions for secure destruction of electronic files.

Entered: 03/07/16 **By:** Stoss, Yasmin

keeping the artifacts for future unrelated projects needs to be stated/ asked about in the consent form. I recommend explaining your intention and giving them the option of including their artifacts in your growing library. The same is true for the videos you want to keep indefinitely. Be specific about how/ in what context you will use these items.

Also, what do you mean by further research? –do you mean only within the context of this study, or do you mean for other research studies? You may have to request permission for setting up a research repository, that is a database for holding data collected for use in multiple research studies that are not specified at the time. For example, there are many medical repositories for blood work that a researcher can go into after the data has been collected and used for a study that the participant wasn't told about specifically (all they did was sign a paper saying their data could be used for research and added to the repository).

Entered: 03/08/16 **By:** Garrett, Michael

Yasmin. I overstated my case the first time. I am not setting up a library in any formal sense nor am I considering a research repository. I merely want to keep the data in secured storage past five years to be available to me as specified in the consent letter:

"In this study, I will use the journals, Flipbooks, and video to look at how people talk and feel when they are describing and explaining the physical world. In addition, I would further like to keep the journals, Flipbooks, and video after my study is finished. I may use these in future research, such as comparing this workshop to others. I may use images or video clips from the workshop in public or online forums, such as national or international presentations, publications, or discussions or in teaching. However, you will not be identified by name or school and any references to these in the clips will be edited out before they are used in this way. If you decide you do not want your journals, Flipbooks, or video clips used in this way, you can opt out by contacting the researcher at any time."

Entered: 03/15/16 **By:** Stoss, Yasmin

PI does not want to set up a repository with these data. He is revising his purpose statement to include a secondary objective.
- per discussion with PI, Yasmin Stoss, and Janine Olive on 3/15

Entered: 03/15/16 **By:** Garrett, Michael

I added this language to the end of my purpose statement in the informed consent: "I also want to understand what teachers do and how they talk when they work to describe and explain the physical world."

I modified the first sentence of the last paragraph in the procedures description in the informed consent: "In this study, I will use the journals, Flipbooks, and video to look at what people do and how people talk and feel when they are describing and explaining the physical world." I included language "to look at what people do and how people talk and feel."

This new consent form is uploaded as an attachment dated 20160315.

The Name-ID correspondence will be deleted from storage. No copies will be kept long term.

Data will be kept indefinitely for further research, educational purposes, and publication. Identifiable information will be edited out of any video data to be shared beyond the research staff. Individual participants will be able to opt out of this use of their data at any time.

I will keep this IRB protocol open and submit further use of this data for IRB approval.

-- Subpage Audio/Video Recording

Describe how the audio/videotapes will be stored.

A master copy of the video data will be saved on a password-protected drive owned by the PI. Master copies may be stored on password-protected secured servers maintain by ETSU on the PI's behalf.

Video selections will be uploaded to secure and password protected accounts only as needed for coding and removed after coding is finished.

Describe how the tapes will be disposed of when the research is complete.

Entered: 02/12/16 **By:** Stoss, Yasmin

Will the master copies be kept after the research period? If so, why?

Entered: 03/17/16 **By:** Stoss, Yasmin

PI is not keeping the data for future unrelated studies. He has updated his purpose statement to include a secondary goal.

All video data will be deleted from any storage set up for coding after the data analysis is finished.

Copies of video data of group activity during the workshop will be edited to remove identifying information (such as personal names and school affiliation) and kept on a password-protected hard drive indefinitely for further research, educational purposes, and publications. Unedited copies will be deleted.

22. Pertinent Literature

Provide a bibliographic listing of pertinent literature.
If preferred you may attach your list using the next question.

No answer provided.

This shows the basis for your proposed study and provides references for the IRB members.

If you did not list above, provide a bibliographical listing of pertinent literature as an attachment.

garrett, m 2016. Seeing the world differently Bibliography.pdf Other

23. Required Attachments PI

Attach Human Subject Training Verification for study personnel who did not complete CITI training through ETSU.

No answer provided.

You do not have to attach verification of CITI training that was completed as affiliated with ETSU.

Attach CV/Resume for Principal Investigator only.

garrett, m 2016. vita.pdf CV

24. Additional Attachments

Attach proposed Informed Consent Document(s).

Entered: 02/12/16 **By:** Stoss, Yasmin

please see the track changes version for revisions

Entered: 02/16/16 **By:** Stoss, Yasmin

If someone wishes to withdraw from the study once they have taken part in some or all of the workshop what will you do with the video? Will you keep the video or ask them if they want to withdraw any clips of themselves? Please state in the ICD what you will do.

Entered: 02/18/16 **By:** Stoss, Yasmin

please answer the above question

Entered: 02/18/16 **By:** Stoss, Yasmin

if you plan to use the recordings for future research please explain that in the consent form. Please be specific about the context in which their recordings can be used.

Entered: 02/18/16 **By:** Garrett, Michael

I moved this language into the "Risk" section:

I may use images or video clips from the workshop in public forums, such as national or international presentations, publications or discussions or in teaching. However, you will not be identified by name or school and any references to these in the clips will be edited out before they are used.

Entered: 03/05/16 **By:** Garrett, Michael

Online survey includes IC statement for survey. Available at https://garrettmd.typeform.com/to/c0DgMO

Entered: 03/07/16 **By:** Stoss, Yasmin

The consent form for the workshop portion is worded as though it is being given before the pre-survey (and as if it includes consent for the pre-survey). Please re-word.

Please see my note above about using data collected in this study for other research.

Entered: 03/08/16 **By:** Garrett, Michael

Thank you, I hadn't thought of that. I reworded the procedures, etc. to reflect the position of this consent as after the online survey. I also broke out the discussion of videotaping in the procedures to make it more clear that I may use clips to look at talk in later research and that I might use video in teaching and professional forums.

Entered: 03/15/16 **By:** Garrett, Michael

I've updated the IC based on our conversation today. See additional notes under "subpage Identifiable data".

garrett, m. Informed consent_track changes 2-12-16.docx	Informed Consent Document
garrett, m. Informed consent. 20160216.docx	Informed Consent Document
garrett, m. Informed consent. 20160218.docx	Informed Consent Document
garrett, m. Informed consent - Online survey. 20160305.docx	Informed Consent Document
garrett, m. Informed consent. 20160308.docx	Informed Consent Document

Template consent can be found http://www.etsu.edu/irb/forms.aspx. Be sure to choose the template that has HIPAA language if your study is accessing or using protected information.

garrett, m. Informed consent. 20160315.docx	Informed Consent Document

Attach proposed Child Assent if your study involves minors and you are not requesting an assent waiver.

No answer provided.

Attach a copy of all advertising materials. Be sure to include ads, letters and telephone scripts.

Entered: 02/10/16 **By:** Garrett, Michael

I am in the process of gathering testimonials from elementary teachers who have participated in professional development with me using a similar technique. The attachment is a boilerplate right now.

Entered: 02/16/16 **By:** Stoss, Yasmin

You will need to provide a completed advertisement before approval can be granted.

Entered: 03/05/16 **By:** Garrett, Michael

The attached flyer is the first draft. As negotiations with the school system proceed, it may be modified.

Flyer advertising the study to prospective participants	Advertisement

Attach Photo/Video Release document if applicable.

Entered: 02/12/16 **By:** Stoss, Yasmin

no this is not necessary since it is covered in the consent form

No answer provided.

Attach any questionnaire and/or survey associated with this study and intended for subject use.

Entered: 02/16/16 **By:** Stoss, Yasmin

Are there not 4 surveys? 2 before, 1 during, and 1 after? if yes please add the missing one here, if not please revise the form to make this consistent.

Entered: 03/05/16 **By:** Garrett, Michael

Online survey is pre workshop. It contains the demographics and the attitude questionnaires. The post-workshop attitude survey will be identical the pre-workshop one, but without the demographics. The workshop evaluation is post-workshop only and will be administered via pencil/paper forms at the end of the workshop. The in-workshop questionnaire is in the form of a teacher journal to be filled out after each component of the workshop.

post only workshop evaluation questionnaire	Questionnaire/Survey
In-workshop attitude questionnaire	Questionnaire/Survey
Online demographics and attitude questionnaire	Questionnaire/Survey

Attach any testing form and/or data collection sheet associated with this study and intended for subject use.

Entered: 02/16/16 **By:** Stoss, Yasmin

If the educational intervention (workshop) is part of the study:
1) Please add a copy of the educational intervention here or at least in summary form.
2)Please attach a copy of the readings you will send the participants

Entered: 02/17/16 **By:** Garrett, Michael

I have not finalized the readings yet.

Entered: 02/18/16 **By:** Stoss, Yasmin

We will need more information about the readings before granting approval

flipbook sketch page. diss.png	Data collection sheet
flipbook text page. diss.png	Data collection sheet
flipbook task page. diss.png	Data collection sheet
Summary of intervention	Data collection sheet

25. Additional Attachments 2

Attach Grant Application if applicable.
Title and PI on the Grant MUST match the title and PI on this application.

No answer provided.

Attach complete protocol.

No answer provided.

Attach Investigator's Brochure.

Entered: 02/12/16 **By:** Cannon, Theresia

This would be appropriate for medical studies. You would not be required to submit a document here.

No answer provided.

Attach Unaffiliated Investigator Agreement if the investigator is not affiliated with ETSU, the VA, or MSHA.

No answer provided.

Attach form 1572 for FDA studies ONLY.

No answer provided.

PI Atttestations

Is there a conflict of interest for the Principal Investigator?
Check the item(s) below that are true.

None of the above

Disclosure of significant financial conflict of interest to the IRB is required for all covered individuals and consultants serving as study personnel involved in designing, conducting or reporting the research presented in the protocol.
The thresholds of ownership described below apply to the aggregate ownership of the individual investigator, his/her spouse, domestic partner,and dependent children (e.g., if an investigator, his/her spouse, domestic partner, and dependent children own together $10,000 or 5% worth of equities in the sponsor, it should be reported below. Do not consider the combined ownership of all the investigators.

Have you collected a completed "Potential Conflict of Interest Form for Study Staff" from every study staff member who will be involved in the designing, conducting, or reporting the research presented in the protocol? (*note: Obtain forms before submission of this form).

Entered: 02/16/16 **By:** Stoss, Yasmin

If they are added as study staff, they will need to complete the Conflict of Interest document.Once collected use the information on the forms to answer the next question

Entered: 02/17/16 **By:** Garrett, Michael

I will do this as staff are added and submit as a modification.

Yes

As the PI, you are responsible for obtaining a disclosure from all study staff members who are involved in designing, conducting, or reporting the research presented in the protocol (anyone with direct contact with participants or direct contact with data collection, reporting or analysis of data, i.e., anyone who could influence outcome of the data). Study staff members must disclose any personal conflict of interest as well as any conflict of an immediate family member. As the PI, you must obtain this disclosure from your study staff by having each person complete the "Potential Conflict of Interest for Study Staff Form." You are responsible for keeping these completed forms with your study records. Audits of these forms may be conducted by the IRB. You are not required to submit thes individual forms from your study staff to the IRB unless your study is selected for an audit of this process.
Click here to download the Study Staff Conflict of Interest Form. Be sure to have these completed before submission of this study as this is an auditable process.

Was a conflict of interest identified for any of the study staff (as defined in IRB Policy 17a)?

No

To see the IRB Policy 17a, click IRB Policy 17a under Policies and Procedures.
If a conflict is present, a Significant Financial Interest Disclosure Form must be completed and submitted by the individual who has a conflicting interest.

26. PI Atttestations

By signing this form, you are attesting that the information contained in this request for project review accurately represents the activities of this project involving human subjects.

You are also attesting that you will promptly inform the Institutional Review Board of any proposed changes in approved research and will not initiate changes without IRB review and approval with the following exception: a change can be made prior to IRB approval when necessary to eliminate apparent immediate hazards to the research subjects. In such a case, you agree to inform the IRB promptly of the change following its implementation (within 10 working days).

You are also attesting that you will promptly inform the IRB of any unanticipated problems involving risks to participants or others (within 10 working days for no-VA studies or 5 days for VA studies).

Student Attestation

By signing this form, you are attesting that you have read and understand your responsibilities as PI outlined in IRB Policy 3 (available on the IRB website). In addition, you are attesting that you agree to comply with all applicable policies regarding human subject research.

pi sig

Enter your password to confirm all the attestations above.

Signed Tuesday, March 15, 2016 5:25:35 PM ET by Garrett, Michael