VirginiaTech

# Institutional Review Board
## Initial Review Application

## Directions

- **Type responses to all questions / requests below. It is recommended that you read through this document before completing.**
- **Do not leave a question blank unless directed. If a required question is not applicable to your study, explain why.**
- **Do not restrict your responses to the space provided. Provide a thorough response to each question. Be as specific as possible, keeping in mind that you are introducing the study to the IRB. Incomplete applications will result in requests for clarification from researchers and will cause delays in review and final approval.**
- **Type responses in the designated shaded boxes or check the designated check boxes.**
- **Use non-technical language throughout your application. Federal regulations require IRB applications to be written in lay language at an 8th grade reading level. Do not use jargon or scientific terms in your explanations/descriptions.**
- **Check for grammatical or typographical errors before submitting. Protocols with substantial errors will be returned for corrections.**
- **This form must be completed and submitted (as a Word document) electronically. Submit all required documents (e.g., Review Form, Initial Review Application, all study forms requested within this application, and bio-sketches) to irb@vt.edu. For questions, contact Carmen Green, IRB Administrator, at ctgreen@vt.edu or (540) 231-4358.**

## Section 1: General Information

**What is the Study Title: The Impact of the Virginia K-3 Primary Class Size Reduction Program on Student Achievement in Reading**

[Note: If this protocol has been submitted to a federal agency for funding, the title of that application **must** match the title of this submission.]

☐ Check this box if this study **only involves the collection or study of existing data,** documents, records, pathological specimens, or diagnostic specimens **and respond only to the following sections within this document:** Section 1: General Information; Section 2: Justification; Section 8: Confidentiality / Anonymity; Section 14: Research Involving Existing Data; and Section 15: Additional Information below (Note: Section 15 is optional).

1. Will this research involve collaboration with another institution?
   ☒ No
   ☐ Yes

   **If yes,**

   A. Provide the name of the institution(s):

   B. Indicate the status of this research project with the other institution's IRB:
      ☐ Pending approval
      ☐ Approved [submit approval letter with this IRB application]
      ☐ Other institution does not have a human subject protections review board
      ☐ Other, explain:

## Section 2: Justification

2. Describe the background of this study, including supporting research: **Since 1998, several schools across the Commonwealth of Virginia have participated in the Virginia K-3 Primary Class Size Reduction Program which provides funding for additional teaching positions in schools with free/reduced lunch rates of more than 16%.**

3. Describe the purpose / objectives of this study and the anticipated findings/contributions: **The purpose of the proposed study is to investigate the perceptions of elementary school teachers and principals regarding the impact of the Virginia K-3 Primary Class Size Reduction Program on student achievement in reading.**

4. Explain what the research team plans to do with the study results (e.g., publish, use for dissertation, etc.): **The study results will be used for dissertation purposes.**

5. Briefly describe the study design: **A random sample of elementary school principals and teachers will complete an online survey containing questions about reading strategies, professional development, and the class size reduction program.**

## Section 3: Recruitment

6. Describe the subject pool, including inclusion and exclusion criteria (e.g., sex, age, health status, ethnicity, etc.) and number of subjects: **The subject pool will consist of 344 elementary school principals and 1,032 elementary school teachers whose schools participated in the Virginia K-3 Primary Class Size Reduction Program.**

7. How will subjects be identified to participate in this research study (If searching existing records to identify subjects, indicate whether the records are public or private. If private, describe the researcher's privileges to the data)? **Public records obtained from the Virginia Department of Education will be used to identify the subjects.**

8. The IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment. Provide an explanation for choosing this population: **The selected population have participated in the program based on the percent of students eligible for free/reduced lunch.**

9. Describe recruitment methods, including how the study will be advertised or introduced to subjects [submit all advertising / recruitment forms (e.g., flyers/posters, invitation letter/e-mail, telephone recruitment script, etc.) with this IRB application]: **All subjects will receive an email containing a letter explaining the purpose of the study, confidentiality of responses, and the option of not participating in the study.**

## Section 4: Requesting a Waiver for the Requirement to Obtain Signed Consent Forms from Participants

**This section (Section 4) <u>not</u> required for studies qualifying for exempt review**

*Many minimal risk socio-behavioral research studies qualify for a waiver of the requirement for the investigator(s) to obtain signed consent forms from subjects [i.e., researcher does obtain verbal or implied (i.e., consent implied from the return of completed questionnaire) consent from subjects; however, does not obtain written consent from subjects]. Examples of types of research that typically qualify for this type of waiver are as follows: internet based surveys, anonymous surveys, surveys not requesting sensitive information, and oral history projects. You may request a waiver of signed consent for either some or all of the study's procedures involving human subjects.*

10. Are you requesting a waiver of the requirement to obtain signed consent forms from participants?
☐ No, consent forms will be signed by all research participants prior to participating in all research procedures [submit consent document template(s) with this IRB application]
☒ Yes

**If yes,**

A. Select **<u>one</u>** of the criteria listed below and describe how your research meets the selected criteria:

☒ **Criteria 1:** [Typically used for anonymous surveys] The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern:

**Or**

☐ **Criteria 2:** The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., sitting down and talking with someone, calling someone at home and asking everyday questions, mall survey, mail survey, internet survey, etc.):

*Either selection of either Criteria 1 or Criteria 2 above, the IRB suggests and may require the investigator to provide subjects with a written or verbal (for telephone interviews) statement regarding the research, which should provide subjects with much of the same information that is required within a consent document. This is typically accomplished by providing subjects with an information sheet (i.e., a document similar to a consent form; however, does not request signatures), supplying the information within the invitation letter, or reading the information sheet to the subject over the phone.*

B. Will you be providing subjects with a written or verbal statement regarding the research?
☒ Yes [submit supporting document(s) (e.g., information sheet, invitation letter) with this IRB application]
**If yes,** check all methods that will be utilized to provide subjects with a statement regarding the research:
☐ Information sheet physically provided to subjects
☐ Information sheet will be read to subject over the phone
☒ Information captured within the invitation document
☐ Other, describe:
☐ No, provide justification for not supplying subjects with this information:

C. Does this waiver of written consent cover all study procedures involving human subjects?
☒ Yes
☐ No, list the study procedures for which this waiver is being requested to cover (Note: a consent document may be required for the study procedures not included under this waiver):

## Section 5: Consent Process

11. Check all of the following that apply to this study's consent process:
☐ Verbal consent will be obtained from participants
☐ Written consent will be obtained from participants
☒ Consent will be implied from the return of completed questionnaire (if the study only involves implied consent, skip to Section 6 below)
☐ Other, describe:

12. Provide a general description of the process the research team will use to obtain and maintain informed consent **and** respond specifically to A-D below:

. A. Who, from the research team, will be overseeing the process and obtaining consent from subjects?

B. Where will the consent process take place?

C. During what point in the study process will consenting occur (Note: unless waived, participants must be consented before completing any study procedure, including screening questionnaires)?

D. If applicable [e.g., for complex studies, studies involving more than one session, or studies involving more of a risk to subjects (e.g., surveys with sensitive questions)], describe how the researchers will give subjects ample time to review the consent document before signing:
☐ Not applicable to this study

## Section 6: Procedures

13. Provide a step-by-step thorough explanation of all study procedures expected from study participants, including the length of sessions involved, and total time commitment: **Subjects will receive a survey via the Internet. A letter will be included with the survey explaining its purpose, confidentiality of responses, and the option to refuse participation in the study. One session will be involved requiring between 15-20 minutes time commitment.**

14. Describe how data will be collected and recorded [submit all data documents (e.g., questionnaire, interview questions, etc.) with this IRB application]: **Data will be collected and recorded from survey responses via Surveymonkey.com.**

15. Where will the study procedures take place? **The study will take place from the participants' computer.**

## Section 7: Risks and Benefits

16. What are the potential risks (e.g., emotional, physical, social, legal, economic, or dignity) to study participants? (do **not** state, "There are no risks involved." Acceptable language = "There are no more than minimal risks involved.") **There are no more than minimal risks involved in this research study.**

17. Does this study involve (check one box): ☒ minimal risk or ☐ more than minimal risk to study participants?
*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 activities or during the performance of routine physical or psychological examinations or tests.*

18. Explain the study's efforts to reduce the potential risks to subjects? **To reduce the potential risks to subjects, the researcher has not included any survey questions which may embarrass or breach confidentiality.**

19. What are the direct or indirect anticipated benefits to study participants and/or society? **The study will benefit participants in the Virginia K-3 Primary Class Size Reduction Program by providing information about perceptions of teachers and principals from across the state.**

## Section 8: Confidentiality / Anonymity

20. Will the study release personally identifying study results to anyone outside of the research team (e.g., participants identified in publications with individual consent)?
☒ No
☐ Yes

**If yes,**

To whom will identifying data be released?

21. Will researchers be collecting and/or recording identifying information (e.g., name, contact information, etc.) of study participants?
☒ No (personal identifying information of participants will not recorded in study files)
☐ Yes

**If yes,**

*The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants. If you need to link subjects' identifying information to subjects' data documents, use a study ID/code on all data documents.*

A. Describe if/how the study will utilize study codes:

B. If applicable, where will the linked code and identifying information document (i.e., John Doe = study ID 001) be stored and who will have access (Note: this document must be stored separately from subjects' completed data documents and the accessibility should be limited)?

22. Where will data documents (e.g., questionnaire, interview responses, etc.) be stored? **Data documents will be stored on the researcher's computer.**

23. Who will have access to study data? **Only the researcher has access to the computer and the data.**

24. Describe the study's plans for retaining or destroying the study data: **The study data will be destroyed after the researcher's dissertation has been defended.**

25. Does this study request information from participants regarding illegal behavior?
☒ No
☐ Yes

**If yes,**

Does the study plan to obtain a Certificate of Confidentiality [visit our website at http://www.irb.vt.edu/pages/studyforms.htm#COC for information about these certificates]?
☐ No

☐ Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form)

## Section 9: Compensation

26. Will subjects be compensated for their participation?
☒ No
☐ Yes

**If yes,**

A. What is the amount of compensation?

*Unless justified by researcher (in letter B below), compensation should be prorated based on duration of study participation. Payment must <u>not</u> be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she must be compensated, at least partially, based on what study procedures he/she has completed.*

B. Will compensation be prorated?
☐ Yes, please describe:
☐ No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study?

## Section 10: Audio / Video Recording

27. Will your study involve video and/or audio recording?
☒ No
☐ Yes

**If yes,**

A. Select from the drop-down box → select one

B. Provide compelling justification for the use of audio/video recording:

C. How will data within the recordings be retrieved / transcribed?

D. Where will tapes be stored?

E. Who will have access to the recordings?

F. Who will transcribe the recordings?

G. When will the tapes be erased / destroyed?

## Section 11: Research Involving Students

28. Does your study include students as participants?
☒ No (if no, skip to Section 12 below)
☐ Yes

**If yes,**

A. This study involves (select all that apply):
☐ Students in elementary, junior or high school (or equivalent)
☐ College students (select all that apply):
  ☐ College upperclassmen (Juniors, Seniors or Graduate Students)
  ☐ College freshmen – please note that some college freshmen may be minors (under the age of 18). If the study meets the specified criteria, the IRB may grant a waiver of parental permission to include these minors without individual guardian permission [see question 32B for further information].

Select one of the following:
☐ These minors will be included in this research
☐ Minors will be excluded from this study. Describe how the study will ensure that minors will not be included:

B. Does this study involve conducting research with students of the researcher? (Note: If it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so):
☒ No
☐ Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation:

C. Will the study need to access student records (e.g., SAT or GRE scores, or student GPA scores)?
☒ No
☐ Yes [if yes, a separate signed consent/assent form (for student's approval) and permission form (for parent's approval if subject is a minor) must be obtained and submitted to the Registrar's office] [submit consent form template(s) with this IRB application]

## Section 11A: Students in Elementary, Junior, or High School

[Answer questions 29 & 30 below if your study involves students in **elementary, junior or high school (or equivalent)]**

29. Will study procedures be completed during school hours?
☐ No
☐ Yes

**If yes,**

A. Students not included in the study may view other students' involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome:

B. Missing out on regular class time or seeing other students participate may influence a student's decision to participate. Address how the study will reduce this outcome:

30. You will need to obtain school approval. This is typically granted by the Principal or Assistant Superintendent and classroom teacher. Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should accompany the approval request to the IRB. Is the approval letter(s) attached to this submission? ☐ Yes or ☐ No, if no, explain why:

## Section 11B: College Students

[Answer question 31 below if your study involves **college students**]

31. Will extra credit be offered to subjects?
☐ No
☐ Yes

**If yes,**

A. Include a description of the extra credit to be provided in Section 9: Compensation above

B. What will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?

## Section 12: Research Involving Minors

**For more information about involving minors in research, visit our website at** http://www.irb.vt.edu/pages/newstudy.htm#Minors

32. Does your study involve minors (under the age of 18) (Note: age constituting a minor may differ in other States)?
☒ No
☐ Yes

**If yes,**

A. The procedure for obtaining assent from these minors and permission from the minor's guardian(s) should have been described in **Section 5** (Consent Process) in this form.

*Researchers may request a waiver of parental permission if the study meets the criteria specified under letter B below. Requesting a waiver for the requirement to obtain informed permission from guardians may be helpful when recruiting college students for minimal risk socio/behavioral research. Most studies involving minors must obtain parental permission prior to the recruitment of minors.*

B. Are you requesting a waiver of parental permission?
☐ No, parents/guardians will provide their permission
☐ Yes, describe below how your research meets **all** of the following criteria:
A) The research involves no more than minimal risk to the subjects:
B) The waiver will not adversely affect the rights and welfare of the subjects:
C) The research could not practicably be carried out without the waiver:
D) (Optional) Subjects will be provided with additional pertinent information after participation:

C. Does your study reasonably pose a risk of reports of current threats of abuse and/or suicide?
☐ No
☐ Yes, thoroughly explain how the study will react to these reports (Note: subjects must be fully informed of the fact that researchers must report reasonable threats of abuse or suicide to the appropriate authorities/persons in the Confidentiality section of the Consent or Permission documents):

## Section 13: Research Involving Deception

**For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at** http://www.irb.vt.edu/pages/newstudy.htm#Deception

33. Does your study involve deception?
☒ No
☐ Yes

**If yes,**

A. Describe the deception:

B. Why is the use of deception necessary for this project?

C. Describe the process of debriefing [submit your debriefing form with this IRB application]:

D. By nature, studies involving deception cannot provide subjects with a complete description of the study during the consent process; therefore, the IRB must waive a consent process which does not include, or which alters, some or all of the elements of informed consent. Provide an explanation of how the study meets **all** the following criteria for an alteration of consent:
A) The research involves no more than minimal risk to the subjects:
B) The alteration will not adversely affect the rights and welfare of the subjects:
C) The research could not practicably be carried out without the alteration:
D) (Optional) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception):

*The IRB requests that the researcher use the title "Information Sheet" instead of "Consent Form" on the document used to obtain subjects' signatures to participate in the research. This will adequately reflect the fact that the subject cannot fully consent to the research without the researcher fully disclosing the true intent of the research.*

## Section 14: Research Involving the Collection or Study of Existing Data Documents, Records, Pathological Specimens, or Diagnostic Specimens

34. Will your study involve the collection or study of existing data?
☐ No
☒ Yes

**If yes,**

A. From where does the existing data originate? **The Virginia Department of Education's website (http://www.pen.k12.va.us) contains Virginia Standards of Learning Assessment results for elementary schools.**

B. Provide a description of the existing data that will be collected: **The researcher will collect Virginia Standards of Learning Assessment results for Grade 3 English from 1998 - present from the Virginia Department of Education's website.**

## Section 15: Additional Information

35. Provide additional information not captured within this worksheet here [response to this question **not** required]: