# Sample IRB

# New Protocol Application

## INSTITUTIONAL REVIEW BOARD

Protocol Application for Research Involving Human Subjects

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**SECTION I:** TYPE OF RESEARCH *(* Refer to "Application Review Categories" in the IRBNet Document Library)*

☒ **Category A**: ☒A(1) ☒A(2) ☒A(3) ☐A(4) ☐A(5)

☐ **Category B**: ☐B(1) ☐B(2) ☐ ☐B(3) ☐B(4) ☐ ☐B(5) ☐B(6) ☐B(7) ☐B(8) ☐ B(9)

☐ **Category C:** Neither category A or B apply.

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**SECTION II:**

1. **Responsible Project Investigator (RPI)**
*(If this is a student thesis or dissertation, the RPI should be the Thesis Committee Chair)*

RPI Name: Gail Burnaford

Appt. Type: ☒ Faculty ☐ Staff ☐ Other

(Note: If other, please state title and attach copy of FAU appointment letter.)

Campus Mailing Address: College of Education, Florida Atlantic University, 777 Glades Road, Boca Raton 33431

Phone: 561-297-2305 E-mail: burnaford@fau.edu

2. **Co-Investigators:** *(If this is a student thesis or dissertation, the student should be listed here)*

Co-Investigator Name: Robin Barkes

Appt. Type: ☒ Faculty ☐ Staff ☐ Doctoral Student ☐ Masters Student ☐ Research Assistant ☐ Undergraduate Student ☐ Other (Please explain):

Mailing Address: AD Henderson University School, 777 Glades Road, Boca Raton, Fl. 33431

Phone: 561-297-3970 E-mail: rbarkes@fau.edu

Co-Investigator Name:

Appt. Type: ☐ Faculty ☐ Staff ☐ Doctoral Student ☐ Masters Student ☐ Research Assistant ☐ Undergraduate Student ☐ Other (Please explain):

Mailing Address:

Phone: E-mail:

Co-Investigator Name:

Appt. Type: ☐ Faculty ☐ Staff ☐ Doctoral Student ☐ Masters Student ☐ Research Assistant ☐ Undergraduate Student ☐ Other (Please explain)

Mailing Address:

Phone: E-mail:

Co-Investigator Name:

Appt. Type: ☐ Faculty ☐ Staff ☐ Doctoral Student ☐ Masters Student ☐ Research Assistant ☐ Undergraduate Student ☐ Other (Please explain)

Mailing Address:

Phone: E-mail:

Co-Investigator Name:

Appt. Type: ☐ Faculty ☐ Staff ☐ Doctoral Student ☐ Masters Student ☐ Research Assistant ☐ Undergraduate Student ☐ Other (Please explain)

Mailing Address:

Phone: E-mail:

3. Protocol Title: Improving Compare and Contast Reading Skills through Think-Alouds

4. College: COE Dept: CCEI Campus: Boca Raton

5. Sponsoring Agency (if applicable)

*(If submitting to funding agency, upload and attach technical portion of grant application to your IRBNet protocol package.)* none

6. Proposed dates for data collection. (*Note: start date must be after submission date of application; allow 4-6 weeks for review)*

Start date: Oct. 9, 2009 (Pending IRB approval from FAU) End date: Nov. 13, 2009

7. Age Range of Subjects: nine through eleven year old 4th grade students

8. Subjects: ☒Normal Volunteers ☐Inpatients ☐Outpatients ☒Minors ☒ Students ☐Disabled Persons ☐Pregnant women ☐Fetuses ☐Individuals with Limited Civil Freedom

9. Total # of subjects: 22

# of Treatment Subjects (If applicable): # of control subjects(If applicable): n/a

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**SECTION III:** Check the appropriate box, where indicated, and respond accordingly. Provide enough detail for IRB reviewers to understand the proposed study. Do not use acronyms or language typical of your discipline. Use language understood in normal conversation. Answer *all* questions to avoid review delays. Type response in grey box.

☐**Yes** ☒**No** **10**. **Will subjects receive payment or extra credit compensation for participation? If yes, specify the amount, form, and conditions of award. The Board must determine whether or not the compensation may coerce the participant. The terms of the compensation and the amount must also be clearly stated in the Benefits section of the consent form**.

☒**Yes** ☐**No** **11**. **Will access to subjects be gained through a cooperating institution? If yes, indicate the name of the cooperating institution and upload and attach a copy of an IRB approval letter from that institution or a letter of agreement to collaborate on this study. The letters must be on official letterhead. (Note: if you are unable to attain this letter until after the FAU IRB has approved the study, please indicate this and assure the FAU IRB in writing that this letter will be submitted upon receipt and prior to data collection.)**

☐**Yes** ☒**No** **12**. **Does this protocol involve investigator(s) at another institution? If yes, explain the details of the collaboration, identify role of each investigator(s) and their institution, and upload and attach a copy of an agreement letter detailing the specifics of the collaboration. This information, if appropriate, would also need to be detailed in the consent form.**

☐**Yes** ☒**No 13**. **Will the subjects be deceived, misled, or have information about the protocol withheld? If so, identify the information involved, justify the deception, and describe the debriefing plan if there is one. Include a copy of the debriefing statement and procedures describing how and when the participants may voluntarily withdraw**.

☒**Yes** ☐**No 14**. **Have you completed the mandatory online training module? Please upload and attach a copy of the certificate along with your package. If you have previously submitted it, note "training on file." (Note: Collaborators and research assistants are also required to submit evidence that they have completed the mandatory training certificate. Anyone interacting with research participants is required to undergo this mandatory training requirement.)**

CITI certificate is attached.

**15**. **Describe the objectives and significance of the proposed research.**

Objectives:

The ability to compare and contrast a story's characters or actions is a difficult reading skill that leaves many young readers struggling and frustrated. It involves higher order thinking skills like synthesis,

analysis and even inferring. After completing a beginning of the school year diagnostic reading test on 22 fourth graders, it was determined that comparing and contrasting is a skill that needed development and improvement. Given a test, which included multiple comparing and contrasting questions, on average the students answered the compare and contrast questions correctly only 70% of the time. With further research, the teacher also determined that previous teachers of these students had been using Venn diagrams to illustrate compare and contrasting in their readings. So the question arises, "Is there another teaching strategy that may be more effective?"

For this study, the teacher will be using the Think-Aloud reading strategy to improve the students' abilities to compare and contrast ideas, characters and actions of various stories. The Think-Aloud strategy involves the teacher reading aloud and modeling various reading skills. For example: connecting, predicting, inferring, questioning, clarifying, summarizing, and evaluating are all strategies taught in the Think-Aloud strategy. What the Think-Aloud reading strategy does not include is comparing and contrasting through analyzing the text. The teacher plans on developing the students compare and contrast reading abilities through teacher modeling during reading aloud, kinesthetic hand motions and student self evaluation of learned reading strategies.

The significance of this study is to determine if the Think-Aloud reading strategy is a more effective strategy in improving students' abilities to compare and contrast ideas, characters and actions in a reading selection. The studies goal is to increase the students' ability to correctly answer compare and contrasting questions 90% of the time.

**16. Describe methods for selecting subjects and assuring that their participation is voluntary. Upload and attach a copy of the consent form that will be used. If no written consent form will be used, you must provide a written justification as to why the IRB should approve a waiver of written consent. You must also include an explanation of the procedures that will be used to ensure that participants are informed and voluntarily agree to participate in the study. (note: sample templates of consents, assents, and scripts are available in the document library as well as additional guidance online at http://wise.fau.edu/research/rcs)**

The subjects in the evaluation will be voluntary. The parents will sign consent forms outlining the details to their participation (see attached). The participanting students will be asked to sign an assent form (see attached). Students and parents will be informed that the students' grades will not in any way be affected by their participation or lack of participation in this study (see attached). All these forms clearly indicate the participation in the study is voluntary.

**17**. **Describe the procedures the participant will follow to participate in this study. Upload and attach copies of all questionnaires or test instruments to your package. If the questions are to be open-ended, provide a sample of the types of questions that will be asked**.

Procedures:

The study will last for four weeks. At the beginning of each week, for approximately one hour, the teacher will model the Think-Aloud strategy. The teacher will use kinesthetic hand motions that correlate with each strategy. When comparing and contrasting an idea, character or action, the teacher will clasp her hands together and while contrasting, the teacher will hold her hands apart. Next the students will work in small groups to read aloud a leveled reading book. This will take no longer than 45 minutes each week. They will be audio taped during these small group-reading sessions. The teacher will later use these tapes to determine if the students are using the targeted reading strategy correctly by tallying the amount of times they demonstrate the skill. The students will be asked to keep a journal after each reading group to write about the reading skill they felt the most comfortable or uncomfortable using and explain why. At the end of the four-week period, the teacher will give the students a reading benchmark assessment that includes various compare and contrast questions (sample of test included). The assessment will take no longer than 150 minutes, broken up into 45 minutes increments, over a period of 2 days. The teacher will analyze the results and determine if the targeted goal of 90% accuracy was obtained.

**18**. **Please indicate whether your data will be anonymous (no identifying information connected to data) or kept confidential (identities are known). If the identities of the participants are known, explain how you will ensure the confidentiality and store the data. Confidentiality of data is required unless justified and agreed to by the participant. Describe any plans for coding data, including where and when data will be stored, for how long and who will have access**.

All data collected in the project will be kept confidential. There will be no students' or teachers' names on any of the data; only coded numbers will be used to identify participants.

Upon collecting the data, the results will be analyzed, evaluated and documented. All data (completed instrument tools, observation notes, and tape recordings) will be kept confidential. Original data will be stored in a locked cabinet in the researcher's office.

**19**. **Describe the risks to the subjects and precautions that will be taken to minimize the risks to the subjects. Risk goes beyond physical risk and includes risks to the subject's dignity and self-respect, as well as psychological, emotional, employment, legal, and/or behavioral risk. There is never "no risk" associated with a study. If there is more than minimal risk, state the level of risk, how you plan on minimizing the risk, and how that risk will be managed. The risk(s) must be clearly spelled out in the consent form**.

All participants in the study are at minimum risks. Students' grades will not in any way be affected by their participation in this study. There is no more risk involved than one would experience in normal classroom instruction.

**20. Describe the benefits of this research protocol to the subject, to science and/or to society. The IRB must have sufficient information to determine whether the benefits of the protocol outweigh the risks. The benefits must also be clearly stated in the consent form.**

1. Evidence of student achievement and teacher learning using documentation methods, assessments, and reflections/reviews.

2. A possible framework for sharing of research based findings on the usefullness of Think-Aloud reading strategies as it pertains to Compare and Contrast reading skills with peers through purposeful reflection and documentation.

## SECTION IV – ASSURANCES (Read Carefully)

By signing this IRB protocol application electronically I, the Responsible Project Investigator, assure the Board that this protocol has been thoroughly reviewed and completed. All protocol questions have been answered clearly. I am familiar with the ethical and legal guidelines and regulations (i.e., The Belmont Report, The Code of Federal Regulations Title 45 Part 46, and FAU's Policy, which are available at http://www.fau.edu/research/rcs/) and will adhere to them. Should any changes occur in the procedures involving human subjects I will submit them to the IRB for review prior to initiating the change. Should I need to modify the protocol procedures, the consent and/or assent documents, I will secure IRB approval before using the revised documents. I will only use the stamped, approved IRB consent and assent documents for use with human subjects. Furthermore, if any problems involving human subjects occur, I will immediately notify the IRB. I understand that IRB review must be conducted annually and that continuation of the protocol beyond one year requires resubmission and review.

## SECTION V – ASSURANCE OF COMPLIANCE AND ADMINISTRATIVE REVIEW

By signing this IRB protocol application electronically I, the Department Chair and/or College representative assure the Board that this protocol has been thoroughly reviewed and completed. All protocol questions have been answered clearly. I am familiar with the ethical and legal guidelines and regulations (i.e., The Belmont Report, The Code of Federal Regulations Title 45 Part 46, and FAU's Policy, which are available at http://www.fau.edu/research/rcs/)

## SECTION VI – ASSURANCE OF SCIENTIFIC AND/OR INSTRUCTIONAL MERIT

By signing this IRB protocol application electronically I, the authorized College official, certify that I have reviewed this research protocol and assurances and I agree that this protocol meets departmental/college standards and attest that the investigator is competent to conduct this research.

*If RPI is also Department Chair then a minimum of one Supervising Authority or Dean's designee must sign off on this application to be submitted electronically to the IRB.*

# Sample Parental Consent Form

## PARENTAL CONSENT FORM

**1) Title of Research Study:** Improving Compare and Contrast Reading Skills through Think-Aloud Reading Strategies.

**2) Investigator(s):** Gail Burnaford, Ph.D. and Robin Barkes (Henderson faculty instructor)

**3) Purpose:** The purpose of this research study is to assess the effectiveness of utilizing the Think-Aloud strategy as it pertains to analyzing and synthesizing types of compare and contrast reading questions.

**4) Procedures:**

Participation in this study will require your child to participate in a weekly leveled reading within a small group of peers. During this time, the group will be audio taped in order for the investigator (Robin Barkes) to analyze the students' ability to effectively use the Think-Aloud Strategy. In addition, your child will be asked to keep a journal of their impressions of the targeted reading strategy. Finally, at the end of the study, your child will be asked to complete a reading assessment which will take no longer than 150 minutes, which will be broken into two 45 minute sessions over two days.

**5) Risks:**

The risks involved with participation in this study are no more than your child would experience in regular daily activities. It is unlikely your child will experience any harm or discomfort. Your child's grades will not be affected in any way by participation or nonparticipation in this study.

**6) Benefits:**

Your child may gain a greater knowledge of reading comprehension skills, in particular as it pertains to compare and contrast questions.

**7) Data Collection & Storage:**

***Any information collected about your child will be kept confidential and secure and only the people working with the study will see your child's data, unless required by law. The data will be kept for 1 year in a locked cabinet [or password protected computer] in the investigator's office and then destroyed.***

**8) <u>Contact Information:</u>**

****For questions or problems regarding your child's rights as a research subject, you can contact the Florida Atlantic University Division of Research at (561) 297-0777. For other questions about the study, you should call the principal investigator(s), Dr. Gail Burnaford at (561-297-2305 and/or Robin Barkes at (561)715-5338***

**9) <u>Consent Statement:</u>**

****I have read, or had read to me, the information describing this study. All of my questions have been answered to my satisfaction. I allow my child _____ to take part in this study. My child can stop participating at any time without giving any reason and without penalty. I can ask to have the information related to my child returned to me, removed from the research records, or destroyed. I have received a copy of this consent form.***

*My child may ____ may not ___ be audiotaped.*

Signature of Parent or Guardian:_____ Date: _____

Signature of Investigator: _____ Date: _____

# Child Assent Template

## CHILD ASSENT FORM

**Improving Compare and Contrast Reading Skills through Think-Aloud Strategies**

Researchers from Florida Atlantic University and A. D. Henderson University School are trying to learn how to improve students' comparing and contrasting skills when it comes to reading comprehension. If you decide to participate in this study, you will be asked to work with your peers each week to read and discuss a leveled reading story. This should only take 45 minutes each week, during which you and your peers' conversations will be tape-recorded. Mrs. Barkes will be using the tape recordings to determine if you are using the taught reading strategy and if so how many times you are using it. Also, each week Mrs. Barkes will be asking you to write a small paragraph on what you like and don't like about the reading strategy. Finally, at the end of the study, Mrs. Barkes will be giving you a reading comprehension test that includes several compare and contrast type questions. She will be looking at your answers to determine if the reading strategy was effective or not. The test is expected to take no longer than 150 minutes, and will be broken up into two 45 minutes sessions over two days.

Mrs. Barkes hopes this study will help improve her teaching methods in reading and your understanding of what a good reader does in order to answer compare and contrast questions correctly.

You do not have to be in this study if you don't want to and you can quit the study at any time. If you ask, your answers will not be used in the study. No one will get mad at you if you decide you don't want to participate.

Other than the researchers, no one will know your answers, including other teachers, parents, friends and other students. If you have any questions, just ask Mrs. Barkes.

This research study has been explained to me and I agree to be in this study.

_____ _____

**Student's Signature for Assent** **Date**

Check which applies (to be completed by person conducting assent discussion):

☐ The subject is capable of reading and understanding the assent form and has signed above as documentation of assent to take part in this study.

☐ The subject is not capable of reading the assent form, however, the information was explained verbally to the subject who signed above to acknowledge the verbal explanation and his/her assent to take part in this study.

_____

**Name of Person Obtaining Assent (Print)**

_____ _____

**Signature of Person Obtaining Assent** **Date**