Office of Research Subject Protections
4400 University Drive, MSN 4C6, Fairfax, Virginia 22030
Phone: 703-993-4121; Fax: 703-993-9590

Human Subjects Review Board (HSRB)

New Submission Checklist

To avoid delay in the processing of HSRB applications, please ensure that the following are included in your application. Applications cannot be reviewed until all of the following checklist items are submitted.

YES	NO	N/A	ITEM
☒	☐	☐	Application with **ALL** sections completed (including check boxes on first page)
☒	☐	☐	Application signed by Principal Investigator
☒	☐	☐	CITI Training completed by all researchers including research assistants
☒	☐	☐	**Proposed Consent Form** (See Template Consent and Consent Guidelines)– All instructional language removed, written at the appropriate reading level for participants
☒	☐	☐	**Proposed Assent Form** (If minors are involved) – Written at the appropriate reading level for the age group (Contact ORSP for a sample of a 6th grade Assent Form)
☒	☐	☐	**Instrumentation** – All surveys, questionnaires, standardized assessment tools, interview questions, focus group questions/prompts or other instruments of data collection
☐	☐	☒	**Recruitment Materials** – Letters to potential participants, advertisements, flyers, listserve postings, emails, brochures, SONA postings, telephone scripts, presentation scripts, etc.
☐	☐	☒	**Grant Applications** – If the research is funded, include the grant application as submitted to the funding agency **(Please note that the HSRB application title must match the grant application title.)**
☐	☐	☒	**Debriefing Form** – If the study proposes to use deception or incomplete information to participants
☐	☐	☒	**Cultural Contact Information** – If the study is being conducted outside the US, the HSRB must inquire about the conduct of research in that country. Submit the name and contact information of an individual who can provide that information.

Applications can be reviewed without the following items, but if they are applicable to the study, they must be submitted before approval can be given.

☐	☐	☒	Research in Mason Classrooms – Submit permission from the instructors
☐	☐	☒	Research in School Systems – Submit approval letter from the school district Human Subjects Review Board
☐	☐	☒	Research in other Universities – Submit approval letter from that University's Human Subjects Review Board
☐	☐	☒	Research in Hospitals – Submit approval letter and approved consent document from the hospital Human Subjects Review Board
☐	☐	☒	Research in Institutions/Organizations without Human Subject Review Boards – Submit permission letter from the institution/organization
☐	☐	☒	If George Mason is the primary recipient of funding, submit Human Subjects Review Board approval from subcontractors conducting human subjects research
☐	☐	☒	Psychology Department – Sign off by the Chair of the Department
☐	☐	☒	School of Management (SOM) – Submit SOM routing form with all approval signatures
☐	☐	☒	Other Mason Committee Oversight– If your study involves the use of blood or other human biological specimens, submit **Institutional Biosafety Committee** approval. If your study involves sources of ionizing radiation or Xray producing devices, submit **Radiation Safety Committee** approval.

George Mason University

Human Subjects Review Board
Application for Human Subjects Research Review

For ORSP Use Only
Protocol No. _____

Federal Regulations and George Mason University policy require that all research involving humans as subjects be reviewed and approved by the University Human Subjects Review Board (HSRB). Any person, (GMU faculty member, staff member, student, or other person) wanting to engage in human subject research at or through George Mason University must receive written approval from the HSRB before conducting research. Approval of this project by the HSRB only signifies that the procedures adequately protect the rights and welfare of the subjects and should not be taken to indicate University approval to conduct the research.

Please complete this cover page AND provide the Protocol information requested. Forward this form and all supporting documents to the Office of Research Subject Protections, MS 4C6. If you have any questions please feel free to contact ORSP at 703-993-4121.

Project Title: The Impact of Using Picture-to-Text Software on Writing Productivity of Young Writers

	Principal Investigator (Must be Faculty)	Co-Investigator / Student Researcher*
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*Student researchers should provide a mailing address rather than campus address. Additional researchers should be listed on a separate page.

Type of Project:
☐ Faculty/Staff Research ☒ Student Project - Please Specify: Graduate
☐ Masters Thesis ☐ Other (Specify):
☐ Doctoral Dissertation

VULNERABLE POPULATION:	PERSON IDENTIFIABLE DATA:	RESEARCH DESIGN:
☐ Fetuses/Abortuses/Embryos	☒ Audio taping	☐ Questions on harm to self or others
☐ Pregnant women	☐ Video taping	☐ Questions on illegal behavior
☐ Prisoners	☐ Data collected via email	☐ Deception
☒ Minors	☐ Data collected via Internet	☒ Human/computer interaction
☐ Mentally disabled	☐ Confidential electronic records	☐ Collection/analysis of secondary data
☐ Emotionally disabled	☐ Coded data linked to individuals	Funding: ☐ Yes ☒ No
☐ Physically disabled	☐ Human biological materials	(If yes, attach copy of grant application)
☐ Undergrad student pool (Psych/SOM)	Biosafety Project #:	Source:
☒ Other: **Specific Learning Disabilities**		OSP Proposal #:

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request and receive approval from the HSRB for changes prior to implementing these changes. I will comply with the HSRB policy for the conduct of ethical research. I will be responsible for ensuring that the work of my co-investigator(s)/student researcher(s) complies with this protocol.

_____ _____
Principal Investigator Signature Date

ABSTRACT

1. Describe the aims and specific purposes of the research project and the proposed involvement of human participants.

   The purpose of this research is to determine the impact of picture-to-text software on the writing performance of young children who have experienced difficulty with expressing thoughts in writing.
   The research questions are:

   1. When using word processing software that pairs a picture with typed words, will a child age 7 to 11 with writing difficulties independently type more sentences that express logical thoughts than if they use traditional paper and pencil to write?

   2. Will having access to picture-to-text software on a word processor help a child with writing difficulties expand the average word per sentence and/or number of sentences on a topic in a four-minute writing sample?

   3. Will a young child with a history of engaging in delaying behaviors begin a writing assignment more quickly when given access to picture-to-text software and a picture prompt for a writing task than if given a picture prompt, paper, and pencil?

2. Describe the characteristics of the intended sample (number of participants, age, sex, ethnic background, health status, etc.).

   The characteristics of the intended sample is 2 or 3 children ages 7 to 11 with difficulties expressing thoughts in writing. The targeted population of students will be healthy, Caucasian, African American, and/or Hispanic male and female children, living in the suburbs of a large metropolitan area on the east coast of the United States. The children chosen may or may not have a disability such as a Specific Learning Disability.

3. Identify the criteria for inclusion or exclusion. Explain the rationale for the involvement of special classes of participants (children, prisoners, pregnant women, or any other vulnerable population).

   The rationale for including children with those characteristics is because the intervention, using picture-to-text software, may assist them with expressing thoughts in writing.

4. Describe your relationship to the participants if any.

   The researcher's relationship with the participants is limited to informal interactions with the families as a friend or neighbor. Although a teacher, she has never taught these children. She is not responsible for giving grades, or evaluations, nor has she ever had direct authority over anyone in the study.

PROTOCOL – Involving Human Participation

1. If there are direct benefits to the participants, describe the direct benefits and also describe the general knowledge that the study is likely to yield. If there are no direct benefits to the participants, state that there are no direct benefits to the participants and describe the general knowledge that the study is likely to yield.

There are no direct benefits to the child as a participant other than to learn to use the software. It is hoped that use of this software for writing practice could positively affect his/her writing skills.

This study is likely to yield the following general knowledge: young children who have difficulties with writing can benefit from having access to assistive technology tools such as picture-to-text software.

2. Describe how participants will be identified and recruited. Note that all recruitment materials (including ads, flyers, letters to participants, emails, telephone/presentation scripts, SONA postings) for participants must be submitted for review for both exempt and non-exempt projects.

   The participants will be identified informally. The researcher will ask friends and neighbors if they know of someone who has a child between the ages of 7 and 11 who has writing difficulties. The researcher will then ask the parents, who were suggested, about their child's age and inquire about writing experiences. If the child fits both criteria, the researcher will ask if they would be interested in having their child participate.

3. Describe your procedures for obtaining informed consent. Who will obtain consent and how will it be obtained. Describe how the researchers will ensure that subjects receive a copy of the consent document.

   The procedures for obtaining informed consent will be that the researcher will explain the study to each participant and guardian and will answer any questions. If the guardian and child agree, an assent form with pictures will be signed by the child and a consent form will be signed by the guardian. There will be two copies of each form, one for the researcher and the other copy for the guardian.

4. State whether subjects will be compensated for their participation, describe the form of compensation and the procedures for distribution, and explain why compensation is necessary. State whether the subjects will receive course credit for participating in the research. **If yes**, describe the non-research option for course credit for the students who decide not to participate in the research. The non-research option for course credit must not be more difficult than participation in the research. Information regarding compensation or course credit should be outlined in the Participation section of the consent document.

   There is no compensation for participation in this study.

5. If minors are involved, their active assent to the research activity is required as well as active consent from their parents/guardians. This includes minors from the Psychology Department Undergraduate Subject Pool. Your procedures should be appropriate to the age of the child and his/her level of maturity and judgment. Describe your procedures for obtaining active assent from minors and active consent from parents/guardians. *Refer to the Guidelines for Informed Consent for additional requirements if minors from the Psychology Subject Pool are involved.*

   The researcher will explain the study to each minor participant and his/her guardian while looking at a written form with pictures to help with the children's comprehension. The researcher will give further explanations if needed and will answer any questions. If the parent and child agree, the assent form with pictures will be signed by the child and a consent form will be signed by the guardian.

6. Describe the research design and methods. What will be done to participants during the study? Describe all tests and procedures that will be performed. Include an estimate of the time required to complete the tests and procedures.

The design of this study is an ABC changing conditions single subject study which consists of:
A. The baseline phase- During these ten to fifteen minute sessions, the child will be provided four pictures and asked to choose two pictures that will be used as writing prompts. The child will be asked to write four or more sentences for each picture prompt. For one picture, the student will write using paper and pencil. For the other picture, the child will type using picture-to-text software on a computer.
B. The software training phase- Each of the 2 – 3 training sessions would last an extra ten to fifteen minutes after the writing samples have been written. The child will learn how to use different features of the picture-to-text software such as; create picture buttons, select words, use the buttons to add words to the sentences, erase words,

add punctuation marks, and listen to the text. When the child can access those features without help or cues, the independent phase will follow.

C. The independent phase- These sessions will be ten to fifteen minute sessions. As in the baseline phase, the child will again be given two prompts and write for a total of eight minutes.

D. D phase will be initiated with a child only if, during the baseline, training, and independent phases there is little or no change in the writing products. During phase D a word box with 16 words would be given to the child with the paper and pencil condition. For the computer condition, a 16 button word/picture pallet would be provided.

There are 2 dependent variables. The first is the number of points earned on each written product using the same data collection sheet. Points will be given for such components as the number of words and sentences written on a topic. The second dependent variable is the number of seconds the child takes to begin writing or typing. There is a place to document the time on the data collection sheet.

The main independent variable is the picture-to-text condition. A second independent variable, a word box with 16 words and typed pallet with 16 words with pictures will be provided as models, only if there is little or no improvement in the writing samples.

The methods will be as follows.

Two writing samples will be taken at the beginning of each session throughout all phases. Because the child is generally given paper and pencil for writing in school, paper and pencil will be the first tools used each session.

Sessions will be held at the child's home or at a quiet setting such as a library depending on the parent request. The child would meet with the researcher for 2 - ten minute sessions per week during the baseline, 2 – twenty to thirty minute sessions per week during training, and for 2 - ten minute sessions per week during the rest of the study for a total of six - eight weeks. Maintenance probes would be taken two weeks after the final session.

At the beginning each session, for each condition, the child will choose one of two picture prompts and then be given a few minutes to independently generate thoughts. A set of writing tools will be prepared for the child to use and a timer will be set for four minutes of actual writing time, the student will begin to write or type about the picture in one or more complete sentences. At the end of four minutes a notation will be made on the word the child is writing or typing. He or she will be allowed to finish his or her thoughts about the picture.

For each writing sample the adult would show the student a picture prompt and say, "Look at this picture. Write four or more sentences to describe what is happening. You will be given a few minutes to think. Then write/type for four minutes. If you would like more time, you may write until you let me know that you are finished."

Two weeks after the final session, maintenance probes will be taken and assessed with both sets of tools. The child will be given a choice of which set of tools to use first.

In order to give insights on attitudes about writing and preferred tools, a short survey will be given to the child and to the parent or legally appointed guardian in both the first and the last sessions.

Materials

In both conditions, a stopwatch will be used to measure how long it takes the child to begin writing after being given the directions and a timer will be used to measure four minutes for the actual writing. For the paper and pencil condition the child will be given a choice of two different types of lined paper, two different types of unlined paper, and several pencils. For the picture-to-text condition the child will have a word processor and picture-to-text software opened to a blank document. For the word box and word pallet condition the picture writing prompt will be

paired with a word box or pallet with 16 words that are appropriate to the picture prompt. The words will reflect what is seen in the picture and will be chosen by the researcher. To provide some standardization, the words and order will be as follows: four nouns, two pronouns, "they" and "them", four verbs, the words "the" and "with", two colors, and two adjectives.

7. Describe how confidentiality will be maintained. If data will be collected electronically (e.g. by email or an internet web site), describe your procedures for limiting identifiers. Note that confidentiality may have to be limited if participants are asked questions on violence toward self or others or illegal behavior. Contact the Office of Research Subject Protections for assistance.

   Confidentiality will be maintained in that each child will choose a name for his/her contributions. When printed out, only the chosen name will be on the writing sample. Only the researcher, guardian, and the child will know the true identity. The surveys will also have the pseudonyms so the answers from the beginning of the study can be compared with the answers at the end of the study. While it is understood that no computer transmission can be perfectly secure, reasonable efforts will be made to protect the confidentiality of your child's writing samples and the digital recordings.

8. Describe in detail any potential physical, psychological, social, or legal risks to participants, why they are reasonable in relation to the anticipated benefits and what will be done to minimize the risks. Where appropriate, discuss provisions for ensuring medical or professional intervention in case participants experience adverse effects. Where appropriate, discuss provisions for monitoring data collection when participants' safety is at risk.

   There are no foreseeable risks to the child for participating in this research.

9. If participants will be audio-or video-taped, discuss provisions for the security and final disposition of the tapes. *Refer to Guidelines for Informed Consent.*

   For the audio taping of the prompt instructions and the software training, there is a section in both forms that will request specific assent and consent to be taped. Both the parent and child must mark the box on the forms must agree to the audio taping. If permission is granted, there will be digital audio recordings of the training sessions and the verbal writing instructions for the picture prompts but there will be no video tapes. While it is understood that no computer transmission can be perfectly secure, reasonable efforts will be made to protect the confidentiality of the digital recordings. The digital files will be kept carefully on a password secured computer. After the research is over the digital files will be deleted.

10. If participants will be misinformed and/or uninformed about the true nature of the project, provide justification. Note that projects involving deception must not exceed minimal risk, cannot violate the rights and welfare of participants, must require the deception to accomplish the aims of the project, and must include a full debriefing. *Refer to Guidelines for Informed Consent.*

    No deception is included in this study.

11. Submit a copy of each data collection instrument/tool (including questionnaires, surveys, standardized assessment tools, etc.) you will use and provide a brief description of its characteristics and development. Submit scripts if information and/or questions are conveyed verbally.

    Copies of the data collection instrument, student and parent survey are included in this submission.

12. **INFORMED CONSENT:** Attach appropriate Proposed Informed Consent document(s). **See Guidelines for Informed Consent and the Template Informed Consent Document for additional information.**

13. **APPROVAL FROM COOPERATING INSTITUTION/ORGANIZATION**: If a cooperating institution/organization provides access to its patients/students/clients/ employees/etc. for participant recruitment or provides access to their records, Attach written evidence of the institution/organization human subjects approval of the project.

PROTOCOL - Involving Existing Records

For the study of existing data sets, documents, pathological specimens, or diagnostic specimens.

1. Describe your data set.

   No existing records will be used.

2. Provide written permission from the owner of the data giving you access for research purposes at George Mason University if the data set is not publicly available.

   No existing records will be used.

3. Describe how you will maintain confidentiality if the data set contains person identifiable data.

   No existing records will be used.

4. Describe what variables you are extracting from the data set.

   No existing records will be used.