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 can not be reviewed until all of the following checklist items are submitted.

Yes	No	NA	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
☐	☐	☒	**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 Universities – Submit approval letter from the University 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	GMU
Protocol No. _____ Proposal No. _____
Classified: ☐Exempt ____☐Non Exempt ☐Expedited
Signature _____ Date_____

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 on the back of this form.
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 Effects of ReadWrite Gold Software Availability on Writing Products of Middle School Students with Special Needs**

Required Data	Principal Investigator (Must be Faculty)	Co-Investigator/Student Researcher*
Name	Dr. Margo Mastropieri	Susan H. Kenney
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Type of Project   ☐ Faculty/Staff Research   ☐ Doctoral Dissertation   ☐ Masters Thesis
☒ Student Project (**Specify** Grad or Under Grad)   Grad   ☐ Other {Specify}

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

*Student researchers should provide a mailing address rather than campus address.
Additional researchers should be listed on a separate page.

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 and/or analysis of secondary data
☒Emotionally disabled	☐ Coded data linked to individuals	
☐Physically disabled	☐ Human biological materials – BioSafety Project #	**FUNDING**: ☐ Yes ☒ No
☐Undergrad student pool (Psyc/SOM)		**Source**
☒Other: LD		(If yes, please attach a copy of the grant application)

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ABSTRACT

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

This is a two part study.
Part II
Six ACPS middle school teachers were trained to use ReadWrite Gold this past summer. With help from the researcher, they would introduce the students to the software and allow the students to use it for writing practice and assignments from one to two times per week for six weeks. Because ACPS is focusing on writing skills this year, the time spent writing would be a normal class activity. All middle school students submit drafts to a web based assessment application called Criterion. Students in the targeted classes would do the same. The control group would type and submit drafts using the Criterion application. The experimental group would type drafts in Criterion but they would have access to a variety of tools as they type.

Part II
 A survey regarding teacher thoughts and attitudes about the use of technology, assistive technology, and ideas for incorporating both, in classes would be sent to middle school Language Arts teachers. This would take about 10-15 minutes to complete and begins with informed consent. If teachers mark the agree button, the survey begins. If they mark disagree, the survey would end. As the survey is begun, an automatic random identifier is assigned to ensure confidentiality.

The final question would ask about interest in participating in an interview. The teachers who would like to participate in the survey would have to type in and e-mail address for contact. Only the researcher would have that information and it would be stripped from the survey to continue confidentiality. Three teachers would be asked to participate in a one hour interview to collect more detailed information about strategies for technology integration and insights as to what may enhance the success of using technology in the classroom for students with documented writing deficits.

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

Part I
Pupils: 20-40 students in grades 6 and 7 between 10 and 13 years of age with mild disabilities. The combined school demographics are   • African American: 44% • Asian/Pacific Islander and American Indian: 5% • Hispanic: 26% • White: 22% It is anticipated that the classes involved will be representative of the district.

Part II

Teachers: 10-20 adults over age 21 will participate in the survey. They are representative of teachers in the district.

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.

Part I
Assistive technology is used by students who have special needs. To see if assistive technology is helpful, that population must be included in the study. It has been determined that only students who have documented needs in the area of written language should have access to this software. Only self-contained special education classes whose teacher signed up for training this past summer, will be allowed to be in this study.
Part II
Teachers must be middle school language arts teachers.

4. Describe your relationship to the participants if any.

Part I and II
I am the Assistive Technology Coordinator of the district. Although I potentially work with any student, teacher, parent related to students who use assistive technology, I am not in a supervisory position over any one in the district. I am never responsible for giving grades, evaluations, nor do I have 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.

Part I
There are no benefits to the students as a participants other than to learn to use the software, have access to a laptop computer for some written work, and to further research in the use of assistive technology with students with disabilities. If the software is found to be beneficial the students will continue to have access to use it for written work. This district has recently purchased ReadWrite Gold software for both middle school buildings. This study could help provide insight as to the benefits of this software for students with special needs. It is hoped that consistent use of this software for writing practice could help improve student writing skills and positively affect the Special Ed student results of SOL Direct Writing Prompt.   The results will also help with the decision, whether or not, to make additional purchases of this software

Part II
There are no benefits to the teachers as a participant other than to further research in the effects of the use of assistive technology for students with disabilities. This study would raise awareness of the teacher attitudes of the use of technology, and assistive technology in particular, by students with special needs, give insights of ways to incorporate the use of assistive technology in special ed classes, and demonstrate benefits from its consistent use.

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.

Part I

Previously, teachers in both middle schools were invited to learn more about the software and attend two workshops in the summer. Six teachers participated and of those, four teach self contained Language Arts classes. Those teachers were chosen to use the software with students. Each of those teachers chose one class to participate. One other self-contained class by each teacher will be the control class.   Students in those classes will be invited to participate in this project.

Part II

For the survey, district survey application will be sent to all middle school Language Arts teachers. Those who agree to the consent form will take the survey. The final question asks if the teacher would like to share insights about using technology with students. Those teachers will be interviewed. If fewer than three teachers agree to the interview, the researcher will ask the literacy coaches for good candidates who use technology effectively.

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.

Part I

For the student group, the researcher will explain the study and answer any questions. She will send an assent form and a consent form with each student with the explanation that they should discuss both forms with a parent or legally authorized representative and then decide. Those who bring back both forms signed will be included in the study. The researcher will also explain the study to the teachers and they will also be asked to sign a consent form. Those who sign will also be included.

Part II

For the survey, the consent form will be the initial question in the survey. If the participant clicks yes, the survey will continue. If the participant clicks no, the survey will express thanks and close.

For the interview, before the interview will begin, the consent form will be reviewed. If the teacher consents by signing, the interview will continue. If he/she does not sign, thanks will be expressed and the interview will conclude. If fewer than three teachers agree to the interview, the researcher will ask the literacy coaches for good candidates who use technology effectively.

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 nonresearch option for course credit for the students who decide not to participate in the research. The nonresearch 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.

Part I
For the student group, the researcher will explain the study and answer any questions. She will send an assent form and a consent form with each student with the explanation that they should discuss both forms with a parent of guardian and then decide. Those who bring back both forms signed will be included in the study. The researcher will also explain the study to the teachers and they will also be asked to sign a consent form. Those who sign will also be included.

Part II
NA

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.

Part I
For the last several years, ACPS middle school Language Arts classes have used Criterion Web based program to improve writing skills. This year ACPS purchased assistive technology software program that has writing tools that can be used by students with writing accommodations and or modifications on their IEP, in conjunction with Criterion.

In this study, students in four self-contained special education classes will use the Criterion Web based program for writing practice as they have done in the past. In four other self-contained special education classes, teachers will train students to use ReadWrite Gold in conjunction with Criterion during writing activities. After training, students will have access to the both software programs one to two times per week for practice with writing assignments.

Student first draft writing samples will be submitted to and assessed by Criterion web based assessment software application. The samples would be from the beginning of the year, without any technology. Then, first draft samples would be submitted to Criterion from the first, third, and sixth weeks of ReadWrite Gold use. Each student ReadWrite Gold profile would be accessed and data from the writing and spelling logs would be gathered. Criterion assigns a holistic score from 1 (poor) to 6 (very well done) and also identifies specific number of errors in spelling, grammar, and content.

Because ACPS is focusing on writing skills this year, the time spent writing would be a normal class activity. All student work will be regular classroom assignments that are requirements of

any sixth or seventh grade Language Arts class. Students will type between 15 and 30 minutes per session for one to two sessions per week. The assessed writing samples will take 30 minutes.

Part II
The survey part of the study would start with an electronic survey regarding thoughts about the use of assistive technology and ideas for incorporating it in classes. It will be sent, via the district survey application, to all the middle school Language Arts teachers in the district. It would take about 10-15 minutes. The final question would ask about interest in participating in an interview. Three teachers would be asked to participate in a one hour interview. If fewer than three teachers agree to the interview, the researcher will ask the literacy coaches for good candidates who use technology effectively.

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.

Part I
Student data in Criterion is password protected. Only the teacher and the student have access to each student's personal records. When printed out the name will be stripped from the copy and a number identifier will replace it.
Part II
The district has an electronic survey program. As the survey is begun, an automatic random identifier is assigned to ensure confidentiality. The final question asks about interest in participating in an interview. The teachers who would like to participate in the survey would have to type in and e-mail address for contact. Only the researcher would have that information and it would be stripped from the survey as soon as it was collected, to continue confidentiality.

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.

Parts I & II
There are no foreseeable risks to students or teachers 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.

Part II
Only the three interviews will be audio taped with informed consent verified. The recording will be digital and will be trashed and purged at the conclusion of the project.

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.

Parts I & II
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.

Part I
Student first draft writing samples will be submitted to and assessed electronically by Criterion web based assessment software application. In addition, user logs and spelling logs are kept by the ReadWrite Gold program. Each student ReadWrite Gold profile would be accessed and data from the writing and spelling logs would be gathered. Criterion assigns a holistic score from 1 (poor) to 6 (very well done) and also identifies specific number of errors in spelling, grammar, and content. Sample materials are attached.

Part II
The Interview and survey are included in this packet. They were created to gather qualitative information and insights as to the current attitudes about technology and assistive technology and successful integration of technology in classrooms.

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.

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PROTOCOL – Involving Existing Records
(For the study of existing data sets, documents, pathological specimens, or diagnostic specimens.)
1. Describe your data set.

In the beginning of the year, each student completes an initial writing piece in Criterion. The scores from that writing would be used as a baseline.

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.

The data is owned by the district included in the study.

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

Each student will be given a number. Names will be stripped from the documents and the resulting number will replace it. Only the researcher will have a key to the identities. The key will be kept secure and destroyed at the culmination of the project.

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

The researcher will extract the baseline holistic score and the identified specific number of errors in spelling, grammar, and content for each student.