RUTGERS UNIVERSITY
Office for Research

eIRB+

Date: Monday, January 27, 2025 2:22:30 PM Print Close

Pro2024002650 View: 1.0 General Project Information

1. General Project Information

INSTRUCTIONS/NOTES: Read and write permissions are determined on this page. Please make sure that all study team members are included on this page. In order to proceed with this application, the individual completing this application must also be listed on this page.

1.0	* **Enter the project title (full title):** The Self-Regulated Learning Diagnostic Inventory: Examining the Psychometric Characteristics of a Situation-Specific Interview of Self Regulated Learning	Full Title of Project: (If Research [Tissue or Data] bank, Enter the Name of Bank)
2.0	* **Enter the project title (short title):** Examining the Psychometric Characteristics of a Situation-Specific Interview of Self Regulated Learning	The short (display) title is the Rutgers internal label associated with this project record. It is utilized as a direct link to this project and is displayed in the "All IRB Submissions" workspace where all activity is listed. This field is limited to 100 characters.
3.0	* **Enter the Principal Investigator / Repository Administrator:** Michelle Russo * **Indicate the current institutional status of the listed Principal Investigator:** Rutgers Graduate Student (Masters and Doctoral Level) * **Faculty Advisor:** Timothy Cleary	For more information on who may be a principal investigator (PI) click HERE Required training for researchers and the research team members click HERE

▶ PI Institutional Status Guidance

4.0 **Study Coordinator / Contact Person:**
Michelle Russo

In addition to the listed PI, select the individual who will be responsible for the day - to - day administrative requirements of the protocol.

5.0 **Co-Investigators:**

Last Name	First Name	Department/Division	School/Unit	Institutional Status	Restricted

There are no items to display

Please refer to your school policies to check who must be included in this section as Co-Investigator

6.0 **Other Study Staff**: (Click on the ADD button below to add Other Staff. Click on the Person's name link below to edit/update)

Name	Dept.	Role	Interaction or Access	Institutional Status	Restricted	Date Modified

There are no items to display

Select each additional personnel or individual to be added. Click on the person's name link to edit/update.

▶ Additional Information:

7.0

*** Is this IRB submission related to an existing OnCore record?**
◯ Yes ● **No**

▶ Guidance for OnCore:

1.1 Submission Type

The IRB Recommendation Tool can be helpful for determining the appropriate application type.

1.0

*** Select the appropriate application type:**
Research Protocol Study (minimal risk) - Expedited/Exempt

*** Is this a Single IRB (sIRB) human subjects study involving multi-center** (external sites) **research with Rutgers as the reviewing IRB?**
● **Yes** ○ No

*** Is this an expanded access protocol?**
○ Yes ● **No**

Application Types:

- ▶ Research Protocol Study (Greater than minimal risk) - Full Board
- ▶ Research Protocol Study (minimal risk) - Expedited/Exempt
- ▶ Secondary Data Analysis Only (Exempt)
- ▶ Research [Biospecimen or Data] Bank
- ▶ Humanitarian Use Device (Full Board)
- ▶ Emergency Use of a Test Article (Expedited)
- ▶ Just In Time (Expedited)
- ▶ Non-Human Subject Research (Including Quality Assurance/Quality Improvement)
- ▶ Administrative Review - (Rutgers U is not the IRB of record)
- ▶ Commercial IRB - WCG
- ▶ Commercial IRB - Advarra
- ▶ Single IRB (SIRB)

▶ Expanded Access (Compassionate Use)

Pro2024002650 View: 3.0 Project Funding

3.0 Project Funding

Funding information related to the project.

1.0	* **Please indicate your current funding source:** Unfunded (PI will absorb all costs)	▶ Additional Information:
2.0	**If applicable, describe other funding source(s) for this project.**	

4.0 Rutgers Affiliated Sites

Specify all sites engaged in this project.

1.0 *** Specify all Rutgers sites engaged in this project:**

University Site	Subjects treated/recruited here	Records, Biospecimens or Data will be:	Is this the Coordinating Site?
GSAPP - CYSEW	no	Stored Analyzed	no

Include the site of your Rutgers affiliation (e.g., The University Hospital, Cancer Institute of New Jersey, etc...)

Include all Rutgers affiliated sites where either data will be stored, data will be collected, participants will be recruited, or you will interact with participants.

▶ Additional Information:

4.1 Non-Rutgers Project Sites

Specify all sites engaged in this project.

1.0 **Domestic Sites:**

	Site Name:	Site Address:	Will subjects be treated/recruited here:	Records, biospecimens or Data will be:	Is this the Coordinating Site:	Rutgers IRB Of Record
View	Union High School	asdf	yes	Collected	no	no

▶ Additional Information:

2.0 **International Sites:**

Site Name:	Site Address:	Country:	Will subjects be treated/recruited here:	Records, biospecimens or Data will be:	Is this the Coordinating Site:

There are no items to display

Additional Guidance

5.0 Biosafety & Radiation Safety

Indicate whether this project involves any of the following:

1.0	* **Indicate if any of the following items are involved in your study:** None of the above	Biosafety Overview and Requirements: Institutional Biosafety Committee (IBC) or contact biosafety@rutgers.edu. ▶ Additional Information:
2.0	* **Will specimens be analyzed and/or processed (e.g., pipetted, aliquoted, centrifuged) in a Rutgers laboratory?** ◯ Yes ● **No**	Institutional Biosafety Committee (IBC) approval is required IF specimens are to be processed/analyzed in a Rutgers laboratory. ▶ Additional Information

5.1 Scientific Review Board (SRB)

Scientific Review Board (SRB) requirements.

1.0

*** Is this a cancer-related protocol involving a Robert Wood Johnson Medical School (RWJMS), New Jersey Medical School (NJMS) faculty member or a CINJ member?**

○ Yes ● **No**

*** Please indicate if ALL of the following apply to this study:**

* Principal Investigator is an RBHS faculty member outside of CINJ **AND**

* Study is either a clinical trial in accordance with the NIH definition OR the study requirements include clinical procedures, such as physical examination, X-ray, clinical laboratory testing, etc., which could potentially be billed to a patient's insurance. **AND**

* Study is conducted at Rutgers or at an affiliated hospital **AND**

* Study is not already under the purview of the CINJ Scientific Review Board

○ Yes ● **No**

*** Does your study meet ALL the following criteria?**

* Principal Investigator is an RBHS faculty member outside of CINJ **AND**

* RBHS investigator-initiated protocol (i.e., not sponsored by industry or an NIH consortium) **AND**

* Entails obtaining consent of study participants

○ Yes ● **No**

▶ CINJ SRB Form Instructions:

▶ For RBHS researchers and study teams outside of CINJ:

6.0 Research Summary

Summary of the research project

1.0

*** Is there an approved Sponsor's protocol, NIH -specific protocol, or lead site protocol for this study?**
◯ Yes ● **No**

Please upload the IRB of Record approved research protocol document and/or the sponsor approved research protocol document in **section 10** when prompted.

For Administrative Review and Commercial IRB (WCG/Advarra) submission types, please indicate 'Yes'.

2.0

* **Study Type** (check all that apply):

Social / Behavioral

Survey

3.0

* **Enter a brief summary of the project:**
The current study examines the psychometric characteristics of a novel, situation-specific diagnostic interview called the Self-Regulated Learning Diagnostic Inventory (SRLDI). This diagnostic interview was developed to evaluate the self-regulated learning (SRL) processes of middle- and high-school students as they prepare for, experience challenges during, and reflect on their performance on common learning activities in schools (e.g., test preparation). In the current project, students will participate in an interview and will complete questionnaires regarding their SRL processes within their Algebra II classes. The current study will focus on generating convergent and predictive evidence to support the validity of inferences generated from SRLDI metrics.

Limit to 250 characters

4.0

* **Select ALL that apply to your study:**

subjects

records

- ▶ Subjects
- ▶ Records
- ▶ Specimens
- ▶ Dyads

Enter the number of subjects:
100

How many records will be reviewed?
100

6.02 Protocol Questions

This section is applicable when there is no Sponsor's protocol, NIH-specific protocol, or lead site protocol for this study.

1.0	* **Purpose/Specific Aims - Clearly state the overall purpose of the study:** The current study introduces a situation-specific interview for self-regulated learning (SRL) with the goal of expanding on the SRL assessment tools available for use in school-based evaluations. Compared to existing SRL assessment measures, the current interview allows for for a more meaningful and situation-specific approach to assessing students' SRL processes. The current interview also uniquely assesses students' responses to the challenges they may encounter while studying for tests in a specific class (i.e., mathematics classes in the current study).	▶ Additional Information
2.0	* **Objectives - Outline specifically what will be achieved by the study.** To date, there is no available self-regulated learning (SRL) interview capable of systematically examining how students approach and react during studying or how they cope with the various challenges they encounter while studying. This study is designed to produce evidence that the current interview is a valid and reliable assessment approach to be used in schools. Specifically, the current study will address the following research questions: 1. To what extent do the metrics generated by the target interview correlate with existing measures of SRL and related processes (e.g., self-efficacy)? 2. To what extent do scores generated from the target interview predict student academic performance in mathematics classes?	▶ Additional Information
3.0	* **Describe underlying reasons/motivations for this project specific to the topic and/or populations being studied OR express any scientific hypotheses that are testable and that include measurable outcomes/endpoints that correspond directly to the objective(s).** The primary reason for conducting this study is to gather empirical evidence to support the reliability and validity of the Self-Regulated Learning Diagnostic Inventory (SRLDI). There there is no known interview capable of generating the data like with the SRLDI, which is geared towards middle and high school students. This study aims to add to the array of assessment measures available to school-based practitioners in their multidimensional assessments of students who may be exhibiting academic difficulties within a particular class or content area.	▶ Additional Information
4.0	* **Research significance - Provide the scholarly or scientific background rationale and significance of the research based on the existing literature and how it will add to existing knowledge** School psychologists and other school personnel spend a large proportion of their professional work assessing the cognitive, academic, and social-emotional functioning of students struggling in school or suspected of having disabilities or diverse learning needs (Benson et al., 2019). Interviews can be a particularly powerful tool in school-based assessments, as informants (e.g., parents, teachers, students) can provide detailed information about a student's functioning, including their behaviors, preferences, strengths, and areas of difficulty (Grapin &	▶ Additional Information

5.0 * **Check off in the table below which identifiers will be accessed/collected:**

None (No identifiers will be collected)

6.0

* **Does this research include community-engaged or community participatory elements?**

◯ Yes ● **No**

▶ Additional Information

Kranzler, 2023). Notably, interviews that school psychologists tend to use in their assessments are typically informal and unstructured and tend to target broad skills or areas of functioning, like a student's overall academic levels or social-emotional functioning (Benson et al., 2019). In contrast, structured interviews are generally underemphasized in educational contexts, even though these types of interviews can provide detailed information about student behaviors and challenges that may not be sufficiently captured by other assessment methods. In addition to the general lack of use of structured interviews in schools, to the author's knowledge, interviews have rarely been used to examine the experiences and skills of students to navigate difficulties or challenges during academic tasks, such as completing lengthy homework assignments in their English Language Arts class or motivating themselves to study for science tests.

The infrequent use of structured interviews in school settings mirrors self-regulated learning (SRL) assessment literature trends. Although school psychologists and other school-based professionals have access to a variety of methods to assess student SRL (e.g., self-report questionnaires and rating scales, think-aloud protocols, direct observations, behavioral traces, and different types of interviews), research shows that they rarely conduct SRL assessments in schools (Cleary et al., 2010; Karlen et al., 2024; Michalsky, 2017), with interviews being one of the least emphasized approaches.

The current study addresses these issues by introducing the Self-Regulated Learning Diagnostic Inventory (SRLDI; Cleary, 2024), a diagnostic interview developed to evaluate the SRL processes of middle- and high-school students as they prepare for, experience challenges during, and reflect on their performance on common learning activities in schools (e.g., test preparation). The SRLDI can be used across classes and content areas and includes questions about how students self-regulate and behave when they encounter challenges (e.g., experiencing anxiety, getting distracted), allowing for a richer and more detailed understanding of the difficulties students may experience during academic activities. The information generated by the SRLDI may add to existing knowledge of students' SRL processes and may inform subsequent interventions for students exhibiting challenges within their classes.

5.0 * **Preliminary data - Describe any relevant preliminary data.** (If you do not have any preliminary data to discuss, please put "N/A")
N/A

▶ Additional Information

6.0 * **Research procedures - Describe all research procedures being performed.**
The prospective research study will be submitted to the International Review Board (IRB) in January 2024 for approval via an expedited review process. The primary researcher will also approach the Union Township school district and target school administration with a proposal regarding the intentions for the current study. The study will be brought to the district's Board of Education members for approval. Upon the study's approval from the IRB, the primary researcher will ask a contact at the high school to administer consent forms to parents of students eligible for participation in the study. Study information and the consent form will be sent to parents via email. All consent forms and study information will first be approved by the district contact before being sent to parents.

The primary author will begin administering the target interview and relevant questionnaires at the target school after consent had been obtained from parents of at least 28 students and will continue with data collection through May 2025, or when data has been collected for 85-100 students. These sample sizes were calculated using Cohen's

▶ Additional Information

(1992) power analysis for detecting a medium- (n = 85) to-large (n = 28) effect size, assuming 80% power and alpha = .05. Two power analyses were run to address the proposed research analyses (i.e., correlation and regression) for both research questions. Verbal assent will be obtained from participating students who had previously had parental consent forms signed and returned. Students will be pulled out of classes during periods that are least disruptive to the students primary course schedule, such as gym class or study hall, to participate in the study. It is anticipated that the administration will take about 40 minutes, or one class period, per student.

Data of student responses will be paired with ID numbers to maintain participant privacy and confidentiality. Of note, the interview and all surveys will be administered using Qualtrics. The author will administer the interview verbally while using Qualtrics to enter student responses. For surveys , students will read questions independently and enter their responses using Qualtrics.

7.0 * **Study duration - Specify the overall duration of the study and the length of time each subject will participate.** ▶ Example

The study is expected to last eight months from recruitment to completion of data analysis. Each participant will commit 40 minutes time on one school day, 25 minutes for the interview and 10-15 minutes for questionnaire completion.

8.0 * **Sample size Justification - Describe and justify the sample size (**The sample size is considered a fixed number that cannot exceeded unless a modification request is made to increase it.**):** ▶ Additional Information

The desired sample size for this study is at least 85 but not more than 100 participants. The sample size of 85 was calculated using Cohen's (1992) power analysis for detecting a medium (n = 85) effect size for correlation coefficients, assuming 80% power and alpha = .05.

9.0 * **Inclusion/Exclusion - Explain the parameters you will use to select records and where you will review these records to abstract data.** ▶ Additional Information

The prospective sample will be recruited from a New Jersey public high school in the New York Metropolitan Area. According to demographic data from the National Center for Education Statistics regarding the 2022-2023 school year, the target school is within a large suburb and serves 2,308 students, with a 13.9 student-to-teacher ratio (National Center for Education Statistics, 2024; Institute of Education Sciences, 2024). Enrollment by biological sex indicates 1,242 (53.8%) male students and 1,066 (46.2%) female students. A total of 733 (31.8%) students are eligible for free or reduced-price lunch. Enrollment by race/ethnicity is as follows: 1,114 (48.3%) Black, 643 (27.9%) Hispanic, 310 (13.4%) White, 186 (8.1%) Asian, 47 (2.0%) Two or More Races, 5 (.0.2%) Native Hawaiian/Pacific Islander, and 3 (0.1%) American Indian/Alaska Native.

All students currently enrolled in Algebra II classes will be invited to participate in the current study. Students will be invited to participate regardless of demographic/identity (e.g., gender, race, ethnicity, socioeconomic status), biomedical, or behavioral characteristics. Students will be invited to participate regardless of academic achievement level or eligibility for special education services. A maximum of 100 participants will be enrolled in this study.

10.0 * **Independent Variables, Interventions, or Predictor Variables - Describe any interventions, treatments, or procedures to be compared for their effects on subjects.** ▶ Additional Information:

This study does not involve the use of interventions or treatments on students, and will only entail collecting data from students using the

target interview and brief motivation and SRL surveys.

1. Level of SRL behaviors exhibited during test preparation as generated by target interview
2. Level of SRL behaviors exhibited during test preparation as generated by the SRSI-SR questionnaire
3. Level of interest in mathematics and related activities
4. Demographic information for the participating students (i.e., gender, race, ethnicity, and socioeconomic status)

11.0 * **Dependent Variables or Outcome Measures - List and describe all outcome measures that "depend on" your intervention(s) or predictor variables.**

1. Academic achievement

List and describe all outcome measures that "depend on" your intervention(s) or predictor variables.

12.0 * **Does this study involve secondary data or secondary specimen analysis?**

○ Yes ● **No**

▶ Additional Information

13.0 * **Does this study involve intervention or interaction with living individuals?**

● **Yes** ○ No

▶ Additional Information

* **Please select any additional conditions that apply:**

Data will be obtained through interaction or intervention with participants.

14.0 * **Describe the qualifications** (e.g., training, experience, oversight) the study personnel listed on the e-IRB Application possess to accomplish their role/responsibilities in the research and noting any period of or limits on availability. When applicable, highlight their knowledge of the local study site(s), culture and society.

▶ Additional Information

The primary investigator (PI) is a doctoral candidate who has completed all academic coursework of the degree. The PI has also served as a research assistant under Dr. Timothy J. Cleary (i.e., dissertation chair), who is an expert in and conducts research on self-regulated learning (SRL). The PI has been a co-author for two articles published by Dr. Cleary on SRL assessment. The PI has been trained on the current study's interview by Dr. Cleary.

It is possible that one or two doctoral students from Dr. Cleary's research team may assist in data collection. If this is the case, the current IRB application will be amended to reflect their inclusion. Any additional study personnel have also been trained extensively in SRL and will complete CITI certifications for working with student participants. These doctoral students have also worked directly with Dr. Cleary to develop the interview being examined in the current study.

Regarding the study site, the PI was raised in the target school's town and attended the target school from 2008-2012. The PI was also a marching band instructor at the target school from 2014-2020 and is familiar with the school's culture and routines.

6.06 Interaction or Intervention with subjects

You have indicated that your research involves interaction or intervention with living individuals.

1.0 * **Vulnerable Populations:**

Students/Employees

Indicate here if any of these vulnerable populations will be enrolled in the research. Review the following guidance to ensure you have sufficient information when specific populations are included in your research study.

▶ Additional Information:

2.0 * **Subject Gender(s)/Identity:**

All Genders

3.0 * **Age Ranges:**

13 - 17 years

4.0 * **Process of Data Collection:** Explain how and by whom data collection will occur or be administered and who will oversee the process.
Data will be collected by the primary investigator (PI), with the data collection process being overseen by the PI's dissertation chair, Dr. Timothy J. Cleary. One to two doctoral students from Dr. Cleary's research team may also assist in data collection; doctoral students who are involved in data collection will be added to the IRB application in an amendment.

Data collection will take place in a quiet, structured location at the target school during the school day, which will be identified by school administration. All interview and questionnaire responses will be recorded via Qualtrics. The PI (and the one or two doctoral students if involved) will ask interview questions verbally and record students' responses via Qualtrics. Students will independently complete several brief surveys immediately following the interview and will enter their responses in Qualtrics.

You must upload all data collection tools in section 10 (Surveys, questionnaires, interview guides, focus group guides, and the like)

5.0 * **Timing and Frequency of Data Collection:** Describe the approximate time and frequency of when data collection will occur.
Data collection will occur over the spring of 2025. Participants will each spend about 40 minutes, or one class period, with the primary investigator during the school day. Data collection will occur approximately 2-3 times per week until students with signed consent forms have participated.

6.0 **Procedures for Audio/Visual Recording:** Describe procedures for audio/visual recording:
There will be no audio/visual recording for this study.

Please indicate in this section whether audio/visual recording is mandatory or optional for study participation.

7.0 * **Study Instruments:** Describe the study instruments for this project:
1. Self-Regulated Learning Diagnostic Inventory

The Self-Regulated Learning Diagnostic Inventory (SRLDI) is a novel, situation-specific, semi-structured interview of SRL designed to assess students' strategic, metacognitive, and motivational processes relative to specific academic activities within a given academic class or context (Cleary, 2024). For the purposes of this dissertation, the interview will be structured to target test preparation activities relative to a specific content area class (2024). Thus, the term test preparation will be used henceforth. The SRLDI was developed and pilot tested by Cleary (2024).

2. Self-regulation Strategy Inventory - Self-report (SRSI-SR)

The SRSI-SR will be administered to students as an existing measure of SRL skills, particularly regarding strategy use. The SRSI-SR is a 28-item self-report questionnaire designed to assess the frequency with which students typically engage in adaptive and maladaptive regulatory behaviors as they prepare for tests (Cleary, 2006; Cleary et al., 2024). Using a 5-point scale ranging from 1 (almost never) to 5 (almost always), students rate how often they exhibit specific regulatory behaviors while preparing for academic tests. For example, students respond to items such as "I ask my teacher questions when I do not understand something" and "I try to study in a quiet place."

3. Task Interest Inventory (TII)

The Task Interest Inventory (TII; Cleary, 2006) is a six-item self-report measure developed to measure students' interest in content area classes and related activities (e.g., science). Students answer questions using a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). Questions include "Learning how to do mathematics is very interesting" and "I like learning about math even when it is difficult."

4. Self-Efficacy for Self-Regulated Learning Scale

The Self-Efficacy for Self-Regulated Learning Scale is a seven-item scale developed to assess students' perceptions of efficacy to self-regulate during mathematics activities carried out at home and school (Pajares & Graham, 1999; Usher & Pajares, 2008). Questions all address different regulatory behaviors (e.g., managing one's time, motivating oneself) and begin with the phrase "How well can you. . ." For example, one full question reads "How well can you finish your math homework on time?" Students answer questions using a 5-point Likert scale, ranging from 1 (not well at all) to 5 (very well).

You must upload all data collection tools in section 10 (Surveys, questionnaires, interview guides, focus group guides, and the like)

▶ Additional Information

8.0 * **Method to Identify Potential Subjects:** Describe the methods that will be used to identify potential subjects.
Any student who is in Algebra II classes at the target school will receive an invitation to participate in the current study.

Please provide details on how you plan to identify individuals who could potentially

		participate in the study. Describe the specific methods or strategies you will use to identify suitable participants for your research.
9.0	* **Recruitment Details:** Describe when, where, how and by whom potential subjects will be recruited. Describe materials that will be used to accomplish your recruitment efforts Students eligible for study participation (i.e., students currently enrolled in Algebra II at the target school) will have consent forms emailed home to parents via PDF by an identified school staff/administrative member. This consent form will be filled out and can be returned via email directly to the PI at the PI's protected school email address. The consent form may also be printed and returned directly to an identified school administration contact. Students whose parents have returned their consent form may participate in the study. When the students are with the PI/research assistant, they will be asked to provide verbal assent. Only students who provide assent will be recruited into the study for data collection.	You must upload your recruitment materials in section 10 (Flyers, social media posts, advertisements, email scripts, phone scripts, screening tools and the like)
10.0	* **Subject Screening:** Describe whether and how individuals will be screened for eligibility and by whom Students enrolled in Algebra II classes at the target school will be eligible for participation in this study.	

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View: 6.07 Interaction or Intervention with subjects - Section 2

6.07 Interaction or Intervention with subjects - Section 2

You have indicated that your research involves interaction or intervention with living individuals.

1.0	* **Privacy Protections During Recruitment:** Explain the measures implemented to safeguard privacy in the process of identifying and recruiting potential participants in the research To ensure the privacy of potential participants during the recruitment process, the following measures will be implemented: 1. Confidential Identification: Recruitment will involve accessing participants through secure databases or lists provided by school administrators. Only de-identified data or minimal necessary information, such as names and contact details, will be accessed. 2. Secure Communication: Initial outreach will be conducted through secure and private channels, including encrypted emails on a computer with a VPN. 3. Consent Form Information: Consent forms will not disclose sensitive information or specific eligibility criteria in a way that could identify participants. Materials will include only general information about the study and an invitation to contact the primary investigator (PI) directly. 4. Optional Participation: Parents of the potential participants will be informed that their child's involvement is entirely voluntary. Data Protection: All recruitment records, including consent forms, will be stored in password-protected files on secure, institution-approved servers or locked physical cabinets at a secure location at Rutgers University. Access will be limited to authorized research team members (i.e., PI, dissertation chair, and trained graduate students in the dissertation chair's research team).	
2.0	* **Consent Process** - Describe the consent process: The consent process will take place via written correspondences through email forms. An identified school an identified school staff/administrative member will email PDFs of the consent form to parents of eligible students. This consent form will be filled out and can be returned via email directly to the PI at the PI's protected school email address. The consent form may also be printed and returned directly to an identified school administration contact. The PI (and any doctoral students involved in data collection if added) will also receive verbal assent from students before beginning data collection in a conversation that is expected to last about five minutes. As part of the assent process, researchers will assess the students' willingness to participate in the study, and the study will stop if the student shows signs of distress or discomfort or if they voice that they no longer wish to participate in the study. Students will be informed that the responses they give will be strictly confidential. Students will also be asked if they have any questions or if they need any aspects of the study/their rights clarified. Separately, the PI and any additional doctoral students involved in data	▶ Consent Requirements

collection will complete online CITI certification training for working directly with study subjects. Researchers in the study will also work directly with the PI's dissertation chair to receive additional training, including how to recognize potential signs of distress or discomfort from student participants.

3.0 * **Expenses** - List all expenses the subject will likely incur by taking part in the research.
There are no anticipated expenses the subject is likely to incur by taking part in the research.

List all expenses the subject will likely incur by taking part in the research. If expenses will be reimbursed by the research, state that here and explain your plan for making such disbursements.

4.0 * **Compensation/Incentives** – Indicate what compensation and/or incentives, if any, will be provided and whether it will be pro-rated depending on what parts of the study the subject completes.
There will be no compensation and/or incentives for participating in this study.

Explain the types of payments to subjects, including justification for the amounts. State the form the compensation or incentive will take (such as cash, course credit, gift certificate, tickets, coupons, etc.) and schedule of payment.

Please refer to the 'Human Subject Payment' policy

5.0 * **Compensation Documentation** - Indicate how you will document that compensation was provided to subjects.
N/A

Indicate how you will document that compensation was provided to subjects. Note: you are required to maintain a full accounting of all funds disbursed to subjects.

6.0 * **Description of Subject Risks of Harm:**
There are no known risks for participating in the current project. That

List the reasonably

	said, it is possible that students may feel uncomfortable talking about their academic performance in a class that is challenging for them, although these risks are small. If this occurs, the primary investigator will take steps to ensure that participants feel comfortable. This may include emphasizing to participants that they do not need to answer any questions if they so desire, as well as making sure they know they can end participation at any point. Students who wish to discontinue participating in the study may do so immediately without question or coercion.	foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Investigators must consider any physical, psychological, genetic, social, legal, economic, privacy and/or confidentiality risks for subjects and/or their families.
7.0	**If Applicable, Describe Risks of Harm to Non-Subjects:** N/A	Describe risks to others who are not subjects (e.g., photographs being collected that might include others in the background, Facebook posts where non-consented individuals post on the subject's feed etc.). Please note N/A of there are no risks to the non-subjects.
8.0	* **Minimizing Risks:** Describe any procedures to be instituted to minimize any reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. In the unlikely event that students get distressed about any aspect of the data collection process, the investigator will seek to remedy the problem as soon as possible by talking directly with the student. The student will be allowed to withdraw from the study at any time and will	Describe any procedures to be instituted to minimize any reasonably foreseeable risks, discomforts,

be informed that they do not have to answer any questions that make them feel uncomfortable or upset.

Additional risks, such as a breach of confidentiality, will be mitigated by only connecting student responses to ID#s during data collection. Student identifying information will not be entered in any database. Moreover, all data collected during this study will be stored in password-protected files on secure, institution-approved servers or locked physical cabinets at a secure location at Rutgers University. Access will be limited to authorized research team members (i.e., PI, dissertation chair, and graduate students in Dr. Cleary's research team).

hazards, or inconveniences to the subjects related to the subjects' participation in the research. Procedures may be needed to prevent additional risks (e.g., encryption methods to prevent a breach of confidentiality for certain types of sensitive data collections).

9.0 * **Will a Certificate of Confidentiality be obtained or applied for?**
○ Yes ● **No**

▶ Additional Information

10.0 * **Potential Direct Benefits to Subjects** - Describe any potential direct benefits that individual subjects may experience from taking part in the research
Students will be asked many questions about their test preparation in their Algebra II classes, including their typical responses to encountering challenges (e.g., difficulties with motivation, anxiety, distractions). It is possible that participation in this study can make students more aware of their thought processes and behaviors in their classes, which may positively impact their approach to studying for tests.

▶ Additional Information:

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View: 6.08 Interaction or Intervention with subjects - Section 3

6.08 Interaction or Intervention with subjects - Section 3

You have indicated that your research involves interaction or intervention with living individuals.

1.0	* **Provide details of your data/safety monitoring plan:** The data collected in this research study will be de-identified. Nevertheless, a cloud-based survey program (i.e., Qualtrics) will be used to safely and securely collect data.	Outline the periodic evaluation plan for collected data on harms and benefits, ensuring subject safety. Specify data types (safety, untoward events, efficacy), review frequency, responsible individuals, initiation date, and data collection methods.
2.0	* **If applicable, detail any plans to establish a data monitoring committee and regularly report committee findings to the IRB and sponsor:** N/A	▼ Requirements Be sure to specify any conditions that trigger immediate suspension of the research. If not using a data monitoring committee, and if applicable, state the statistical tests that will be used for analyzing the safety data to determine whether harm is occurring.
3.0	**Describe your plan, if any, to share research results with subjects.** Data results will not be shared with the subjects.	Describe your plan, if any, to share research results with subjects. When applicable, if results to be

shared are clinically actionable, provide evidence of appropriate lab certifications (e.g. CLIA) providing the results and qualifications of the study staff who will return such results.

4.0 * **Describe your plan, if any, to share aggregate research results with study subjects.**
Aggregate research results will not be shared with the study subjects.

5.0 * **Describe the data analysis plan.**
Data will be entered using SPSS. Descriptive statistics will be conducted to describe the sample demographics and research variables used in the analyses, which will include frequency counts and percentages. Pearson correlations will be used to determine convergence levels between the interview metrics and other SRL measures and measures of self-motivational beliefs (e.g., task interest, perceived instrumentality, self-efficacy for SRL behaviors). Regression analysis be used to examine the extent to which interview metrics can predict academic achievement in students' Algebra II classes (i.e., Semester I final Algebra II grades and midterm scores) while controlling for other measures (e.g., gender, ethnicity, SES).

Describe the data analysis plan. Where possible, include any discipline-specific analytical or statistical procedures and/or for qualitative research, please provide a concise explanation of your data analysis approach. Be succinct in detailing how you intend to analyze and interpret the data, as applicable to the research.

6.0 * **Describe the steps that will be taken to secure the data through all phases of the research.**
Paper materials associated with this project will be locked in a file cabinet in the Graduate School of Applied and Professional Psychology at Rutgers University for five years, after which they will be destroyed. Paper materials will be limited solely to any consent forms returned to the school via a physical copy. Data collected for this project will be collected via computer through Qualtrics, and there will be no physical copies of responses. These data will be downloaded from Qualtrics onto a harddrive of an encrypted, password-protected computer that will be stored in a locked research office at Rutgers University. Only the PI, trained graduate students who have completed IRB training at Rutgers, and Dr. Timothy J. Cleary will have access to the collected data and the original protocols of this project. In addition, the subject's identity in the database will be represented by a numeric code rather than their name.

▶ Requirements

After the data is analyzed, the link between the coded data and the identifying information of the individuals will be destroyed.

7.0 * **Please describe a plan to assure subject privacy and the confidentiality of subject data.**
To protect the privacy of all participants and to ensure confidentiality of student and teacher data, participants will be identified only by a random number.

▶ Requirements

8.0 * **Describe your plan to share the results of your research.**
The results from this study may be used to publish additional dissertations in the future. Additionally, the data collected from this study may be used for future research projects and may be shared with the scientific community if published. All participant information will be de-identified for future research projects. While individual results will not be shared with participants or the target school, the results reported in the prospective dissertation will be shared with school administration.

Describe your plan to share the results of your research. This includes plans to share results with the scientific community, participants, or others.

9.0

* **Will the data/specimens collected during this research be stored for future use?**
● **Yes** ○ No

* **What data elements and/or type(s) of specimens will be stored:**
Participant survey responses, interview responses, and background information (e.g., gender, age, achievement variables, ethnicity, etc.) will be stored at Rutgers University following data collection. The stored data will not include any participant or parent identifying information, with all participant information being paired with random ID#s.

* **Please confirm whether the data and/or specimens collected in this research will be stored and distributed to other investigators for future research:**
● **Yes** ○ No

* **Describe the details of any plans to share the data with other researchers (with or without identifiers) for secondary research.**
The data shared with other researchers for secondary research will be de-identified. This data will include background/demographic information (e.g., gender, age, achievement variables, ethnicity, etc.), as well as participant responses.

* **Please specify the Rutgers IRB-approved Research Repository and IRB Protocol Number where the data and/or specimens will be stored OR, if it is not a Rutgers IRB-approved Repository, state the name/address of the Repository:**
Graduate School of Applied and Professional Psychology
152 Frelinghuysen Rd
Piscataway, NJ 08854

6.1 Clinical Trial Information

NIH Definition of a Clinical Trial - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

1.0

* **Does this study have an interventional research design to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes?**

○ Yes ● **No**

* **Will this study be registered on clinicaltrials.gov voluntarily?**

○ Yes ● **No**

In a clinical trial, interventional is defined to mean that human subject participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect(s) of the intervention(s) on a health-related biomedical or behavioral outcomes.

See NIH FAQ

▶ Additional Information

7.0 Drugs/Devices/Biologics

A drug study, device study, biologics study, and humanitarian use device study are all different types of research studies that involve different types of products.

1.0 * **Indicate all that are involved in this project:**

None of the above

A drug study, device study, biologics study, and humanitarian use device study are all different types of research studies that involve different types of products.

- ▶ Drug
- ▶ Device
- ▶ Biologics
- ▶ Humanitarian Use device

8.0 Informed Consent

Human Research Protection Program Toolkit - A comprehensive set of forms, templates, policies, procedures, and guidance topics to support the ethical and compliant conduct of Human Subject Research and its oversight.

1.0 * **Will subjects be asked to provide their informed consent to participate in research?**
Yes, all

You must upload all relevant Adult Consent, Assent, Parent/Guardian Permission, Surrogate Forms into section 10.

* **Is this a greater than minimal risk study?**
○ Yes ● **No**

Inclusion of standard Rutgers University injury disclaimer is not required in the consent document.
☐

A subject provides informed consent by doing any of the following:

• Physically document/sign, eSign/enter their name into a consent form

• Verbally agree to participate in the research

• Review the consent statement prior to participation and complete the research activity (survey, focus group, etc.).

Select options based on the target population and identify who will provide consent for participants in the research study.

8.1 Informed Consent Process

For more information, go to HSPP Toolkit Forms & Templates Special Consent Considerations.

1.0	*** Please indicate if any of the following apply to your research:** None of the above	▶ Consent Requirements ▶ Outline plans to enroll individuals:
2.0	*** Location of Consent Process and Protecting Privacy:** Consent forms will be sent via written correspondence (i.e., email) with parents. The assent process with participants whose parents have already provided consent for their child to participant in the research study will occur within the target school.	Indicate where the consent process will take place and outline provisions made to protect subjects' privacy during consent discussions (this includes adult consent, assent, parent/guardian permission/and surrogate consent).
3.0	*** Ongoing Consent:** The duration of the subjects' participation in the research is not expected to exceed one hour. Thus, there are no plans to re-contact subjects or their parents to obtain additional assent/consent.	If the duration of subjects' participation in the research is lengthy, outline any plans to re-contact them to determine whether they have any questions or concerns about continued participation in the research (this includes adult consent, assent, parent/guardian permission/and surrogate consent).
4.0	*** What are the individual roles for researchers involved in the consent process?** The principal investigator (PI), Michelle R. Russo, will be responsible for collecting consent forms from parents. The PI will also be responsible for speaking with participants to attain assent for participation in the styd.	Indicate the roles individual study members listed in the application will have in the consent process (this includes

		adult consent, assent, parent/guardian permission/and surrogate consent)' Revise to 'Specify the roles that each study member, as listed in the application, will undertake in the consent process (this includes adult consent, assent, parent/guardian permission/and surrogate consent).
5.0	* **Consent Discussion Duration**: Consent forms will be sent home via written correspondence. The letters sent to parents should take no longer than one-to-two minutes to read.	State the length of time that will be devoted to the consent (this includes adult consent, assent, parent/guardian permission/and surrogate consent) discussion and any waiting period between the consent discussion and obtaining consent.
6.0	* **Coercion or Undue Influence**: Consent will be obtained independently from parents and children to ensure both parties agree without undue influence. Study participation will take place in a familiar, non-threatening environment such as a school library or classroom during the school day, with familiar staff members nearby. The primary investigator (PI) will be trained to recognize signs of discomfort or distress in children, who may choose to opt out at any point during study participation. Separately, the PI will maintain regular communication with school administrators to address any concerns about undue influence or coercion.	Outline steps that will be taken to minimize the possibility or perception of coercion or undue influence. When some or all of the subjects are likely to be vulnerable to coercion or undue influence —such as children, prisoners, adults represented by a surrogate, students, economically or educationally disadvantaged individuals—

		outline additional safeguards you have included in the study to protect their rights and welfare.
7.0	*** Subject Understanding:** Study procedures and rights will be explained in terms the participants can understand, ensuring they grasp the voluntary nature of participation and their right to opt out. Participants will be asked if they understand what is being asked of them, as well as if they have any questions about any aspects of their participation in the study.	Outline steps that will be taken to ensure subjects comprehend the key study elements.
8.0	*** Indicate the types of consent that will be involved in this project** (check any or all that apply): Written permission for a minor will be signed by a parent or legal guardian Assent by a minor will be documented	
9.0	*** Are you requesting a waiver of certain elements normally required in the consent form?** ○ Yes ● **No**	Select YES, if you are requesting a waiver of one of the eight elements listed below) ▶ Eight elements normally required: ▶ Additional Guidance
10.0	*** Are you requesting a waiver of some of the elements required to be included in the HIPAA Authorization?** ○ Yes ● **No**	For the IRB to grant an alteration of the HIPAA authorization, the study must be no more than minimal risk to subjects. ▶ The core elements of a valid authorization include:

10.0 Attachments

Required attachments for this submission.

1.0 * **Consent Documents:**

Name	Version Number	First Name	Last Name	Created Date	Modified Date

There are no items to display

* **Recruitment Materials/Data Collection Tools** (flyers, brochures, advertisements, study tools, etc.):

Name	Version Number	First Name	Last Name	Created Date	Modified Date

There are no items to display

Site Approvals (Domestic/International Site approval)**:**

Name	Version Number	First Name	Last Name	Created Date	Modified Date

There are no items to display

Other Supporting Documents (e.g., OCRA confirmation)**:**

Name	Version Number	First Name	Last Name	Created Date	Modified Date

There are no items to display

▶ Additional Information:

2.0 **Please include any additional information that was not provided in this application.**

Pro2024002650 View: Final Page

Final Page

Submission Summary:

SUBMISSION TYPE: Research Protocol Study (minimal risk) - Expedited/Exempt
REVIEW TYPE - REQUESTED: Expedited
IRB SUBMISSION ID: Pro2024002650

Next Steps:

Submit study for IRB review:

Your application form **will not** be submitted for review until the Principal Investigator returns to the study "workspace," and clicks on "**Submit Study**". You can track the status of this study's submission by logging into the study workspace.

To submit the study:

1. Ensure that you have answered all questions in the application and all sections are error-free.
2. Click on "**Save & Exit**" to exit the application and return to the "workspace."
3. Navigate to the left of your screen, and under "My Activities," click "**Submit Study**" to initiate IRB review.

Pro2024002650

View: eIRB+ Add a Rutgers Site

Study Site(s) & Location(s)

INSTRUCTIONS:

- Use this form to complete the information about only study site(s) engaged in this research where Rutgers University is the IRB of record.
- You may add multiple study sites by clicking the **'OK and Add Another'** button.

1.0

* **Site:**
GSAPP - CYSEW

* **Site Address:**
sss

Performance Site(s)

Human Research Protection Program (HRPP) Toolkit | Rutgers Research

2.0 * **Subjects will be recruited/treated here:**
◯ Yes ● **No**

3.0 * **Records, biospecimens or data will be:** (select all that applies)

Stored

Analyzed

4.0 * **Summarize other activities that will take place at this site:**
Data Analysis

5.0 * **Is this the coordinating site?**
◯ Yes ● **No**

▶ Coordinating site information

Pro2024002650

View: eIRB+ add a Non Rutgers Site

NON - RUTGERS SITE(S) Domestic

INSTRUCTIONS:

- Use this form to indicate the non-Rutgers domestic site(s) engaged in this research
- You may add multiple non-Rutgers domestic site(s) by clicking the **'OK and Add Another'** button.

1.0

*** Site Name:**
Union High School

*** Site Address:**
asdf

Click here for more information on Performance Sites

2.0

*** Are you requesting that Rutgers serve as the IRB of Record for this site?**
◯ Yes ● **No**

*** You must upload in section 10 IRB and/or Ethics Committee approval, letter of collaboration, or contract for the site indicated.**
☐

IRB of Record: An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution and is designated to do so through an approved Assurance with OHRP.

If you are requesting that Rutgers serve as the IRB of Record, please contact the IRB Reliance Administrator to set up a Pre-Consultation meeting at IrbRelianceteam@research.rutgers.edu

3.0

*** Subjects will be recruited/treated here:**
● **Yes** ◯ No

4.0

*** At this site, records, biospecimens or data will be** (select all that applies)

Collected

5.0

*** Is this the coordinating site?**
◯ Yes ● **No**

▶ Coordinating site information:

6.0

*** Summarize activities that will take place here:**
Data Collection