Date: 6-3-2023

IRB #: IRB-2023-597
Title: Impact of Virtual Reality on Developing English as a Foreign Language Learners' English Conversational Skills for Situated Learning
Creation Date: 4-3-2023
End Date:
Status: Approved
Principal Investigator: Victoria Lowell
Review Board: Exempt Reviewer and Admin Office Actions FY23
Sponsor:

Study History

Submission Type Initial	Review Type Expedited	Decision Approved

Key Study Contacts

Member Victoria Lowell	Role Principal Investigator	Contact vllowell@purdue.edu
Member Weijian Yan	Role Primary Contact	Contact yan400@purdue.edu

Initial Submission

Study Personnel

*required

Study Personnel

In this section you will name all staff who will participate in the study.

Be certain that all personnel have completed online training prior to submitting the protocol or it will be returned without review.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear when you click "View". If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.
Name: Victoria Lowell
Organization: PWL CURRICULUM & INSTRUCTION
Address: 100 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: vllowell@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

To speed up the request for access, please have the person submit this electronic form to the HRPP.

- *First Name - Last Name*

- *Purdue e-mail address*
- *Purdue departmental affiliation*

*required

Please check your Purdue University PI classification.

✓ Faculty (tenured, tenure-track, research, and clinical)

Student

Purdue non-faculty or non-tenure track faculty member granted special PI status.

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: Weijian Yan
Organization: PWL CURRICULUM & INSTRUCTION
Address:
Phone:
Email: yan400@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

To speed up the request, please have the person submit this electronic form to the HRPP.

- *First Name - Last Name*
- *Purdue e-mail address*
- *Purdue departmental affiliation*

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study. The PI defines the roles of each staff member based on the definition below.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Be certain that all personnel have completed online training prior to submitting the protocol or it will be returned without review.

Yes

✓ No, the only personnel on the project are the PI and Point of Contact.

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study. The PI must have their role(s) listed in the box below.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.

Prof. Victoria Lowell Principle (faculty), will oversee all aspects of the study design and conduct.

Weijian (Michelle) Yan, (graduate student) will assist with the study design, instruments, and analyzing the collected data.

Our contact person is Dr. Li Yang, lecturer in the Department of Translation and Interpretation, School of Foreign Languages, Jiangsu University of Science and Technology. She will analyze de-identified data.

Research Sites

*required

Where will the study take place?

Check all boxes that apply.

Purdue University

✓ Data collection occurs via Internet/Electronic Survey/Online.

*required

Is there a specific site or service that will be utilized?

(e.g. MTurk, Prolific, Qualtrics)

✓ Yes

*required

Please list the name of the site(s) or service(s) used for data collection.

We will use Purdue Qualtrics for collecting data from Pre-Survey and Post-Survey.
We will use VR app-Immerse to have the Pre-test and Post-test activities and the 6 workshops.
We will use Purdue Zoom to record the pretest and post-test activities, the 6 workshops, and the interviews.
We will use Purdue Box for data storage.

No

✓ External Site (non Purdue University)

*required

Please list the external sites. Keep in mind that later in the application process, you will be asked for appropriate permission letters to document the site's agreement to allow your team to conduct research.

China- Jiangsu University of Science and Technology

*required

Are any of the sites outside of the United States?

The IRB may need to make special considerations when reviewing international research.

✓ Yes

No

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. Several tools for protocol development and Quick Reference Guides, are available on our website and additional links are included throughout the application.

Be certain that all personnel have completed online training prior to submitting the protocol.

Helpful Tip: Use the Create PDF button at the top of the page if you need to share a PDF version of this protocol for discussion with a reviewer outside of the Cayuse system.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Some types of research involving minimal risk to participants is considered under the exempt category. Exempt research still requires review by the Human Research Protection Program through submission of this application. Please see here for more descriptions.

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

Research that does not fit into an exempt category typically involves the collection of new data from an interaction or intervention with a participant.

Common Examples include:

✓

- *Prospective collection of biological specimens for research purposes;*
- *Collection of data from voice, video, digital, or image recordings made for research purposes;*
- *Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.*

I need to know if my project is considered "Human Subjects Research"

Just-in-time request from sponsor

Just in time submissions may be utilized if sponsor requires information prior to making an award to the researcher, but there are significant delays in the ability of the study team to identify the methods that will be used to conduct the human subjects research. (NIH example here.)

Select this option if you have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but the application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible and defined at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a Just-in-Time/Development protocol. Some sponsors may choose to withhold some or all funds.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

When the study design is finalized. Please submit a NEW PROTOCOL to the system.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

Note, this submission type is used for activities involving Health Care Operations it should only be used for activities assisting a Covered Entity (typically a medical/psychological health care

provider) in their assessment of medical outcomes.

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral (also called reliance) asking that the review be deferred to one institution's Institutional Review Board (IRB).

This applies to non-exempt research only. A collaborating institutions' IRB will need to conduct their own IRB review of their Investigators' activities and determine if they are exempt or engaged in the research.

To save time, please see instructions and definitions at this link on our website.

I would like to register to keep a subject registry or participant pool.

Occasionally colleges or departments create subject pools to communicate research opportunities to students or those who fit specific inclusion criteria and are interested in regular research participation.

Student subject pools are usually comprised of undergraduate students enrolled in particular courses requiring participation in one or more research projects.

Research Classification and Special Considerations

*required

Would you determine that this research is predominately social or biomedical in nature

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When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

Biomedical
My research has a biomedical focus.

✓ **Social / Behavioral**
My research has a social or behavioral focus.

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Target Recruitment of Potentially Vulnerable or Special Populations
Examples: Children, Pregnant Women/Fetuses, Prisoners, those that lack capacity to consent), economically disadvantaged persons, minorities.

Clinical Trial
PLEASE READ ALL OF THESE DEFINITIONS CLOSELY.

NIH
NIH defines a Clinical Trial as "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."

ICJME

International Committee of Journal Medical Editors (ICMJE) defines a clinical trial as "any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome."
http://www.icmje.org/about-icmje/faqs/clinical-tri...

If either the NIH or ICJME definition applies to this study, please check this box.

BESH
Alternatively, there are also definitions (but less guidance around) Basic Experimental Studies involving Humans (BESH). https://grants.nih.gov/policy/clinical-trials/besh.htm

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

Data and Safety Monitoring Plan
Used to monitor clinical research or research where more regular, continuous risk assessments can be made for protection of the enrolled study population.

International Research
✓ *This protocol includes research that is conducted at a non US location.*

Data Controlled Under HIPAA
Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies. Click here if your study will use Protected Health Information.

Research with student records controlled under FERPA.
Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Community-engaged research
This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

Incidental Findings
Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the

study. (e.g. genetic data, MRI or test results).

Biological Specimens Repository

This protocol involves the establishment of biospecimens for future use. Repositories involve prospective collections of data that are processed, stored and distributed to multiple investigators for use in research.

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.
Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

Background and Significance

Give a brief summary of your study in simple terms. In a few sentences, describe why you are conducting the study.

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

Speaking skills are crucial for language learners. Exposure to a target foreign language environment when learning a language allows language learners to experience and react to context-related factors when learning to converse in a language (Moeller & Catalano, 2015). However, many foreign language learners lack access to an environment to practice speaking authentically, which may result in unsatisfactory performance in language speaking (Chen & Hwang, 2020). Engaging language learners in authentic, interactive, immersive, and meaningful learning in realistic contexts can assist them in improving their conversational skills. Virtual reality (VR), with its unique affordances (e.g., immersion, presence, interaction), has been considered a viable environment for language learning (Lan, 2020) to practice and improve conversational proficiency and develop linguistic competence and confidence (Scavarelli et al., 2021). VR can provide language learners with realistic sociocultural contexts, and guidance can be provided to facilitate their interactions in real-life situations (Chen & Hwang, 2020).

English-speaking self-efficacy can be defined as English learners' confidence in their ability to speak English effectively. It can determine the effort, involvement, and determination a person puts into achieving a goal (Schunk, 2003). Research has indicated that self-efficacy has a tremendous impact on English learners' language performance and there is a positive correlation between English self-efficacy and achievement (Rahimi & Abedini, 2009).

Lave and Wenger (1991) believe knowledge is only present in the situation where learners must participate in the process and explore the materials in the context to truly understand the significance and usefulness of knowledge. Learning is a social process during which knowledge is constructed and learning takes place in authentic physical and social and cultural contexts (Dawley & Dede, 2014; Falconer, 2013). Therefore, Herrington and Oliver (2000) suggested instructors should provide authentic contexts that reflect the way the knowledge will be used in real life and authentic activities to enable situated learning. Because all learning takes place in a specific context and the context significantly impacts learning (Yasin et al., 2012), VR can be an ideal technology tool to help enhance conversational English proficiency

through situated learning. Falconer (2013) concluded that exercises in VR can offer effective opportunities for situated learning as VR can satisfy two key elements of situated learning-authenticity and social interaction.

In this research project, we hope to discover whether speaking simulations in virtual reality can improve English as a Foreign Language (ESL) learners' conversational speaking skills, the relationship between speaking self-efficacy and conversation performance, the relationship between attitudes towards technology and conversation performance and understand ESL learners' overall perceptions of application of VR-assisted instruction on developing situated learning. We hope the findings can provide guidance for educators who want to integrate VR into language teaching and learning.

*required

Research Questions and/or Hypotheses

Please list any relevant study hypothesis/hypotheses and/or research questions. If this does not apply, type "Not Applicable".

Do role-playing speaking simulations in a VR application (e.g., Immerse) improve ESL learners' conversational English skills?
Is ESL learners' speaking self-efficacy correlated with their conversational English performance? (If it is correlated, how is it correlated?)
What are ESL learners' attitudes toward VR technology for language learning?
Is ESL learners' attitude toward technology correlated with conversational English performance? (If it is correlated, how is it correlated?)
How do ESL learners perceive their experience with a VR application (e.g., *Immerse*) to develop situated learning?
Do learners' perceptions of situated learning impact their self-efficacy or performance?

*required

How long will participants be asked to be in the study?

How long will participants be asked to be in the study? What can a participant expect?

List the approximate duration in the fashion below.

- *Number of occasions for data collection =*

- *Approximate minutes or hours per occasion/interaction/intervention=*
- *Single day or multiple days?*
- *Total amount of time (in hours, days, or months) until all data are collected from a single participant =*

If more than one timeline exists based on study arms, please include this description for each population/group.

In the first week, participants will fill out a 30-minute presurvey and participate in one 90-minute VR training on using a VR program- Immerse. For this program, we will be using the desktop version of Immerse.

In the second week, participants will have one 90-minute pre-assessment using the VR platform Immerse through their desktop computer.

From the third week to the eighth week, the participants will participate in one 90-minute instructional workshop in the VR platform Immerse on conversational speaking simulations once a week for six weeks.

In the ninth week, participants will fill out a 30-minute post-survey and have one 90-minute post-assessment.

Students may also volunteer to participate in a semi-structured 60-minute interview in the tenth week.

A student may be in the study for approximately 15.5 hours for 10 weeks.

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do. Briefly explain the methods in the box below. Attach information about research instruments, interventions, or assessments in the attachment section below.

First, our contact person, Dr. Li Yang will assist our team by asking the administrator in the Department of Translation and Interpretation if they would send a recruitment letter to the freshmen in the School of Foreign Languages, at Jiangsu University of Science and Technology, inviting the students to join the research study, which includes eight workshops aimed at improving conversational skills using a desktop-based VR- Immerse. The administrator will send the recruitment letter to all freshmen in the School of Foreign Languages, at Jiangsu University of Science and Technology.

Freshman students who receive the email and are interested in participating in the study will email the researchers for more information or to sign up for the research study. The researchers will provide the potential participants with any information requested and ask the potential participants if they meet the inclusion criteria, and also check that they should not be excluded.

Next, the researchers will email the potential participants consent forms to complete and return to the researchers. After receiving the completed consent forms, the researchers will register students/participants.

Next, the participants will be sent a presurvey. The information on the presurvey (and post-survey) is related to the research questions. We are investigating the correlation between speaking self-efficacy and conversation performance, attitude toward technology with conversation performance, and students' perception of using desktop-based VR to facilitate situated learning. All the scales on self-efficacy and attitude towards technology are validated and cited from published peer-reviewed papers.

After filling out the presurvey, the researchers will hold a training session with all participants in the VR platform Immerse to learn how to navigate it. All participants will be trained together in one training session because the workshops involve task-based role-playing learning activities and participants will learn how to complete activities as a group.

The training session and the eight workshops will be conducted on the desktop-based Immerse VR platform. Participants will use a desktop computer, with a keyboard and a mouse when completing the activities and interacting with other participants in the VR environment. No other equipment is needed. Participants can be seated during the learning process. Participants can choose any space in which an internet connection or Wi-Fi is available for the training session and eight workshops. For example, they can choose their dormitory, classroom, or any place on campus because the university has Wi-Fi everywhere on campus.

After attending the training session as a group, participants will participate in eight 90-minute workshops using the desktop version of the Immerse VR platform, completing conversational speaking role-play simulations. The sessions will be facilitated and taught by a third-party American instructor who has been teaching conversational English online for many years.

The first workshop will be conducted in Immerse Scene-Backyard Barbecue and recorded in Zoom. It is a pre-assessment of English conversational skills at the outset. Participants will see a backyard with a swimming pool, chairs, a table, and snacks for a barbecue party. Participants are requested to greet and introduce themselves to a new friend and find out personal information about him or her, engaging in a free-style 10-minute conversation on any topics they are interested in. Please refer to the picture-Backyard barbecue in the attachment to view the scene.

The last workshop will be conducted in Immerse Scene-City Center and recorded in Zoom. It is a post-assessment of English conversational skills after completing the learning workshops in Immerse. Participants will see a city with a subway, taxis, and high-rises in Immerse. They are requested to discuss with their partners three types of transportation in this city, compare the advantages and disadvantages of each transportation method, and decide on a method to reach a destination. Please refer to the picture-City Center in the attachment to view the scene.

The rating rubrics of conversation performance for the pre-assessment and post-assessment are adapted from the FSI Proficiency Rating as cited in Higgs &Clifford, (1982). It evaluates five areas: accent, grammar, vocabulary, fluency, and comprehension. Each area can be rated from point 1 being the least satisfactory to point 6 being the most satisfactory. Please refer to Conversation Assessment Rubrics in the attachment for more details. As the instructor is located in the U.S., he can access Zoom. Chinese

students can access Zoom too as they can join a meeting instead of hosting a meeting in Zoom. The data will be transcribed and rated by researchers and saved in Purdue Box.

During the six instructional/learning workshop sessions with speaking simulation activities, students will engage in six task-based role-play learning activities to improve their conversational skills on accent, grammar, vocabulary, fluency, and comprehension. All videos will be recorded in Purdue Zoom and saved in Purdue Box.

In the first instructional workshop, participants will access Immerse Scene-Airport Departure where they will see an airport terminal with a checking-in desk and security check and etc. (please see the picture -Airport Departure in the attachment for more details). Participants will be divided into pairs and engage in role-play speaking activities as passengers and airport staff to practice checking in at the airport and going through security, while also incorporating modal verbs-must, should, can, and would like to. All related vocabulary and grammar will be learned in this 90-min workshop and participants will also receive scaffolding from instructors and feedback from peers.

In the second instructional workshop, participants will access Immerse Scene-Fast Food where they will see a fast-food restaurant (please see the picture Fast Food in the attachment for more details). Participants will be divided into pairs and engage in role-play speaking activities as guests and cashiers to practice ordering fast food at McDonald's while incorporating comparative and superlative adjectives. A menu is provided for vocabulary learning and feedback from peers and the instructor will address the five areas of vocabulary, accent, grammar, fluency, and comprehension.

In the third instructional workshop, participants will access Immerse Scene-Kitchen where they will see a kitchen with different foods and utensils (please see the picture Kitchen in the attachment for more details). Participants will be divided into pairs and engage in role-play speaking activities as cooks and hosts to practice speaking cooking methods in a fun and interactive way while learning sequencing words and phrases such as First, Next, and Finally. Feedback from peers and the instructor will address the five areas of vocabulary, accent, grammar, fluency, and comprehension.

In the fourth instructional workshop, participants will access Immerse Scene-Shopping Center where they will see a shopping mall with clothes and other shopping items (please see the picture Shopping Center in the attachment for more details). Participants will be divided into pairs and engage in role-play speaking activities as shoppers and sales assistants to practice shopping for clothes while learning Present Tense. Feedback from peers and the instructor will address the five areas of vocabulary, accent, grammar, fluency, and comprehension.

In the fifth instructional workshop, participants will access Immerse Scene-Restaurant where they will see a restaurant with chairs, tables, drinks, and cups (please see the picture Restaurant in the attachment for more details). Participants will be divided into pairs and engage in role-play speaking activities as customers and waiters to practice ordering in a restaurant while learning Conditional Sentences. Feedback from peers and the instructor will address the five areas of vocabulary, accent, grammar, fluency, and comprehension.

In the sixth instructional workshop, participants will access Immerse Scene-Hotel Room where they will see a hotel lobby with a check-in front desk, luggage, and sofa (please see the picture Hotel Room in the attachment for more details). Participants will be divided into pairs and engage in role-play speaking activities as guests and hotel staff to practice checking in a hotel room with the Simple Future

Tense. Feedback from peers and the instructor will address the five areas of vocabulary, accent, grammar, fluency, and comprehension.

For detailed lesson plans, please refer to Lesson Plan in the attachment.

Of the participants who agree to be interviewed (questions on the post-survey), 5 volunteers will be selected. During the interviews, participants will be asked to describe their perceptions of VR-assisted instruction. The interview protocol is adapted from Herrington & Oliver (2000) in which researchers change the multimedia to Immerse. It investigates participants' perceptions of the application of Immerse to facilitate situated learning. The interview will be conducted in Zoom and the transcript will be saved in Purdue Box.

A sequential explanatory mixed-method design will be used for data triangulation (Creswell & Clark, 2017). In the quantitative strand, a quasi-experimental study will be conducted to examine the correlations between speaking self-efficacy and conversation performance, attitude toward technology and conversation performance.

In the qualitative strand, a case study design will be employed to explore learners' experiences with Immerse in more depth in explaining quantitative results.

Quantitative data. For the strand of the quantitative study, we will conduct pre- and post-assessment and self-report surveys. The surveys use a 5-point Likert scale (1 = "Strongly disagree", 5 = "Strongly agree").

A pre-assessment and post-assessment will be conducted as conversation role-plays to examine students' English conversation performance based on an established rubric.

Surveys: a pre- and post-survey will be conducted at the beginning and the end of the research study respectively. Survey items are focused on students' perceived speaking self-efficacy and students' attitudes toward technology.

Qualitative data. The results of quantitative data analysis will inform the design of qualitative data collection (exploratory) and analysis. For the qualitative strand, we will combine data from multiple sources including observational notes on students' interactions, feedback, and performance during the learning process and semi-structured interviews with five students.

Data Analysis and Interpretation
Quantitative strand. The descriptive statistics from the surveys on perceived speaking self-efficacy and attitude toward technology will be presented followed by inferential statistics using correlation.

Qualitative strand. We will use Nvivo for data management, analysis, and mapping. The recordings of the interviews will be uploaded to Nvivo along with the transcripts for coding. There will be two cycles of coding (Miles et al., 2014; Saldana, 2013) for both thematic analysis and content analysis. Each of the researchers will review the same transcript and create a codebook for the rest of the coding process for consistency and transparency. The codebook will be expanded and reorganized based on new emerging codes in the process. Categories and themes will be generated based on the relationships across the codes. Frequencies of words and codes will also be checked. The relationships among the identified key concepts will be examined. The findings of the qualitative strand will be interpreted to explain quantitative

results with rich descriptions.

Attach any surveys, questionnaires, assessments

For purposes of recordkeeping, the HRPP/IRB will need to have a Word or PDF version of any Qualtrics or electronic survey questionnaires. ***Please include more than a link to the survey.***

conversation assessment rubrics-IRB2023597.pdf

Interview Protocol and Rationale-IRB2023597.pdf

Lesson Plans-IRB2023597.docx

pre survey and post survey-IRB2023597.docx

airport departure-IRB2023597.png

backyard barbecue-IRB2023597.png

city center-IRB2023597.png

fast food-IRB2023597.png

hotel room-IRB2023597.png

kitche-IRB2023597.png

restaurant-IRB2023597.png

shopping center-IRB2023597.png

In long term studies, a visual representation of a timeline about the participant's role in the study is helpful.
If this applies to your project, you may upload a visual representation as a Word (.docx) or PDF file here.

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time line for participants-IRB2023597.pdf

References

If you've referenced other studies in your description of of the project above, or if you feel that IRB would find these helpful to review the risks, benefits, or items that affect participant understanding, please include citations here. Otherwise, indicate "Not Applicable."

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Other Study Background and Significance Information

If additional information is needed about your study, the IRB may ask you to include more information in this box.
Otherwise, this field may be left blank.

Participant Information

*required

Total Study Enrollment

Please enter the number of subjects that will be enrolled at all sites, that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a study modification.

We are planning to enroll 16 participants.

*required

Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

We are investigating EFL (English as a Foreign Language) learners' English conversational skills in China. Foreign language refers to a language that is not widely used by the people of that country. We will not need a larger number than 16 students to participate. If a student withdraws and another student wants to participate, we may accept another participant.

*required

Age(s) of Participants in Study Population

If the research has multiple subject groups, select all that apply.

Please include any age-related assessments of assent or consent in the appropriate sections of this application.

Newborn to less than 1 year old

Children, ages 1 to 17

✓ Adults 18 years and older

*required

Please enter the anticipated age range(s) of adults who will be eligible for participation in your study.

Freshmen students in Chinese universities with most being 18 years or older.

*required

Are you specifically recruiting adults with potential cognitive or decision making impairment?

Please include any information about eligibility or screening in the Inclusion/Exclusion Criteria questions below.

✓ The target population does not specifically include adults with cognitive or decision making impairment.

The target population specifically includes adults with cognitive or decision making impairment.

The target population includes a combination of adults with and without cognitive or decision making impairments or where potential participants have a vast range of cognitive or decision making abilities.

Unknown- Data are deidentified of any age or dates of birth.

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

We will only enroll participants who are more than 18 years old. In addition, English is a foreign language for the potential participants.

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone who is younger than 18 years old and whose mother tongue is English will be excluded from the research.

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

- ✓ Yes, a known group or subject pool.
- No, only the general population
- Both a known group AND also the general population.

*required

Please identify any known groups, participant pools, or records that will be used for recruitment purposes.

- Health or Education Records
- Purdue University student subject pool
- ✓ Other methods to recruit from a pre-defined population or pool

*required

Please describe the recruitment methods.

Describe the other method used to pre-identify a study population.
If the study involves an educator/student, employer/employee relationship, please explain the methods used to eliminate coercion.

We will recruit potential participants from all freshmen currently registered in the Department of Translation and Interpretation at the School of Foreign Languages of Jiangsu University of Science and Technology. We will send emails to invite them to join the research study. The workshops are being offered to complete the research study. For those interested in participating in the research, we will give a training

session on how to use VR app-Immerse before the learning activities begin.

The complementary classes are provided to students for free. Students can voluntarily participate in the study. Whether the students participate in this research project or not has no impact on their grades in their courses or their standing with the university.

*required

Privacy During Recruitment

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc. If your study is not anticipated to generate privacy concerns during recruitment, please state this below.

The department administrator will send a recruitment letter to all freshmen currently registered in the Department of Translation and Interpretation from the School of Foreign Languages of Jiangsu University of Science and Technology. Students interested in the study will send emails to the researchers and the researchers will send the emails to potential participants individually so that they can't see other participants' contact information.

Dr. Li Yang is a contact person at the school, and she is the dean of the Department of Translation and Interpretation. Dr. Li Yang has given permission to complete the study in their department as she is interested in improving their programs' instruction and learning. Dr. Li Yang is not currently teaching the target population and is, therefore, not an instructor for the potential participants. Dr. Li will participate in reviewing the deidentified data for improvement in their teaching at the school.

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

Yes

✓ No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

✓ Direct mail/email

*required

Upload the recruitment letter that will be used.

Recruitment letter-IRB2023597.docx

Flyers/Brochures

Published Advertisements

Verbal Scripts

Website

Social Media

Other

None of the above

Risks and Benefit

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

---

*Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. P**lease note that all research exposes to subjects to some risk.***

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

VR can be generally divided into two types: desktop-based VR and head-mounted display (HMD)-based VR (Cheng & Tsai, 2019). Desktop-based VR is displayed on a flat screen and controlled via a keyboard or mouse, while HMD-based VR allows users to view the virtual space through VR headsets and interact through headset buttons, controllers, or haptic systems (Dhimolea et al., 2022). As we are using desktop-based VR, participants won't put on headsets and they will only need a computer, keyboard and a mouse for this learning experience.

Desktop-based VR provides significantly less immersion. Therefore, although some users may have some discomfort from motion sicknesses, the more significant symptoms a user may experience from using a headset for lengthy periods of time (e.g., lightheadedness, dizziness, headache, nausea, version problems, or drowsiness and fatigue) are unlikely to occur.

To minimize risks from physical issues, the instructor will conduct a verbal wellness check after 20-minutes of instruction to ask how the participants feel. If the participant reports any symptoms, the instructor will have the participant take a break from or terminate the instruction.

There is the potential risk of a breach of confidentiality. We will collect student names. After the data collection is complete, we will code the surveys, assessments, and interviews to reduce this risk. The raw data and key for the codes will be stored in Purdue Box.

We are unaware of any risks that would lead to significant harm.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*
- *Are medical or psychological resources available that participants might require as a consequence of the research?*

VR is a powerful pedagogical tool to develop language learners' speaking competence (Gruber, 2021). Students have reported that VR can provide a more natural conversation setting than a formal academic environment (e.g., a classroom) to enhance target-language speaking (Enkin, 2022). VR can also offer a more interactive, context-embedded, and immersive learning environment (Bahari, 2021), reduce speaking anxiety (Abal, 2012; Chen & Hwang, 2020; Melchor-Couto, 2017; Thrasher, 2022), promote motivation (Chen & Hwang, 2020; Liaw, 2019), increase knowledge acquisition and retention (Chang et al., 2012), improve students' willingness to communicate (Ebadi & Ebadijalal, 2020), improve oral output and attitudes toward foreign languages (Lan, 2014), and improve creativity and agency (Kaplan-Rakowski & Gruber, 2021; Xie et al., 2019). Students have reported greater enjoyment in the speaking activities in VR than in face-to-face settings (Enkin, 2022). Some students have found their speaking sessions realistic and immersive (Chen & Hwang, 2020), and the feeling of authenticity inspires their learning motivation (Wu & Hung, 2022). VR can enable users to build skills to have conversations without fear of the social consequences that can be present in the physical world (Steward Rosenfield et al., 2019).

Dr. Victoria Lowell is very experienced in VR and she has published multiple papers on VR applications in educational settings. Weijian Yan has been teaching Chinese students English for 15 years as a lecturer in a Shanghai university. They co-authored a paper "Facilitating Foreign Language Conversation Simulations in Virtual Reality for Authentic Learning". Therefore, they are qualified to do the research.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

✓ The researchers believe the study is no greater than minimal risk.

The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

✓ Yes, there are potential benefit(s) to be gained by the individual subject/participant.
*required

Please list the potential benefit(s) to the individual.

VR-assisted instruction can provide the participants with an authentic learning environment that facilitates the development of English conversational skills. The skills can help participants better communicate with native speakers, promoting personal growth and future career.

Yes, there are potential benefits to be gained by society.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

We are unaware of any potential harm. Participants will be provided with more opportunities to practice their English conversational skills in a more authentic learning environment. They may spend a little time getting familiarized with the VR platform which may increase some learning curve.

Privacy and Confidentiality

*required

Privacy During Data Collection

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves. Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or completing other tasks.

The pre-survey and post-survey will be delivered electronically through Purdue Qualtrics. Students may take the surveys wherever they would like.

The pre-assessment and post-assessment and 6 workshops will be conducted in the virtual reality platform Immerse, and video will be recorded through Zoom provided by Purdue University and saved into Purdue box.

The semi-structured interview will be conducted through Zoom provided by Purdue University. The recorded interviews will be saved to Purdue Box.

The transcripts of the recorded interviews will be saved to Box. we will use Kaltura to transcribe the video recordings (Please see Kultura Security and Privacy Policy in the "Other Attachments").

Participants choose their own place to study and provide data for the surveys so there is no concern about privacy.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

The data will be kept in Qualtrics and Purdue Box. Only investigators can have access to the data.

We will keep the signed consent forms for a minimum of three years after the closure of this study.

The data on pre-survey and post-survey, pre-assessment and post-assessment, interviews, and recordings of 6 workshops will be maintained for current and future research presentations and reports.

We have plans to use audio-visual recordings and/or direct quotes from the interviews for future research as we want to investigate conversational interaction in English-speaking learning activities.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

The data will be kept in Qualtrics and Purdue Box. Only investigators can have access to the data. The data will be de-identified in data analysis and future publications.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

After the survey reports are collected, we will de-identify the data. The code key and deidentified data will be kept for future research.

After the pre-assessment in the second week of the research project, the VR video recordings will be transcribed in a month. After the post-assessment is done in the eighth week of the research project, the VR video recordings will be transcribed in a month. After the interview is done in the ninth week of the research project, interviews will be transcribed in 1 month.

Once the VR recordings and interview are transcribed, we will keep the original audio-visual recordings for the following 5 years as we plan to further develop this line of research on using VR for assisting EFL learners with developing their speaking skills. The data in the audio and video recordings will be transcribed in order to encode and provide a rich, detailed description of the actions and language production. we will follow a "data-driven" multimodal conversation analysis approach which allows for detailed analysis of "ways of seeing, knowing, cognition, embodiment, tools and technologies and teamwork"(Jewitt et al., 2016, p.102) by making visible phenomena that participants in the interaction may not be entirely aware of at the time. We will keep original audio-visual recordings because some information when conversing will not show up in a transcript, and it may be important for reanalysis or for future studies.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

✓ No, this study will not require a CoC.

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

---

*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

Yes

✓ No

*required

Please provide information on the reason(s) that compensation will not be offered to participants.

This research provides more opportunities for participants to improve their English conversational skills. At present, we don't have any funding to provide any compensation to participants.

International Research

Research conducted by Purdue University investigators falls under the university's purview and guidelines even when conducted elsewhere. If research is conducted internationally, the project must also have been approved by the local equivalent of an IRB or Ethics Committee before it can receive final approval from the Purdue IRB.

When there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. In most situations, the IRB requires documentation of this local approval before it gives its approval. Please see the guidance for researchers engaging in international research.

---

*required

Provide a brief overview of sites of international research and any known laws or regulations regarding human research protections applicable to any of the non-US sites.

We are planning to do the research with Jiangsu University of Science and Technology in China where there is no IRB site for social science.

*required

Is there an IRB, ethics committee, or other community body which reviews human subjects research for the non-US site(s)?

Yes

✓ No

*required

Describe any current social, cultural, economic, and political considerations for the non-US site(s) which may impact the research, including consent and/or assent considerations.

---

none known.

*required

Describe the experience and/or other qualifications the investigators have related to conducting the research with the local community/culture. Describe if the investigators have the knowledge or expertise of the local or state or national laws that may impact the research.

The investigators must understand community attitudes to appreciate the local laws, regulations or norms to ensure the research is conducted in accordance with U.S. regulations as well as local requirements.

The team of investigators includes an international student- Weijian Yan- who is familiar with local communities and culture. She is a Chinese national. She had been teaching Chinese students English at Shanghai Sanda University for 15 years before she came to study at Purdue in 2021.

*required

If the investigator is working with local collaborators (Local Co-PI) please describe this arrangement. Please include information about the background and experience of the local collaborator as it pertains to this research protocol. Also describe the allocation of responsibility for the various research related activities.

If the researcher is a student, describe how the student will communicate with the principal investigator during the conduct of the research and how the principal investigator will oversee the research.

Investigators are not working with local Co-PIs.

Dr. Li Yang at Jiangsu University of Science and Technology holds a Ph.D. degree in Language Education from Auckland University and she has been teaching English speaking, listening, writing, and reading at Jiangsu University of Science and Technology for more than 15 years. Dr. Li Yang is on the ground in China facilitating the research. She will be responsible for helping to access potential participants from Jiangsu University of Science and Technology. After researchers collect and deidentify the data, she will involve in analyzing the deidentified data and writing manuscripts with the researchers.

*required

List the main language(s) spoken by the study population.

Chinese, but they are learning to speak English.

*required

Are the PI and/or study team members who will be on site fluent in the language(s)?

✓ Yes

No

*required

Provide a description of the context of cultural norms or local laws and differences with U.S. culture with respect to research, autonomy of individuals or groups, consent procedures, recruitment techniques, age of majority, requirements for parental consent, etc. Include an explanation of what cultural considerations will be required to conduct this study.

With respect to research, the main difference between the US and China is that there is no formal institutional review board for human science research. China does have an ethics committee for medical research. In China, people who are 18 or above attain legal adulthood and are regarded as independent, self-sufficient, and responsible. All participants in our research study are above 18. There are minimal cultural considerations that need to be taken into account for this study as students have already used computers in their daily life.

*required

If this research involves a population or community with limited resources, describe how the research is responsive to the health needs and the priorities of the population or community and how any intervention or product developed, or knowledge generated will be made reasonably available for the benefit of that population or community.

This research intends to introduce virtual reality as an educational tool to improve EFL teaching and learning. Most of Chinese universities still rely on textbooks to improve their English-speaking skills. While these textbooks are usually outdated, they don't provide an authentic learning environment. Students also find that compared to the academic environment, VR can create a more natural conversation setting to enhance the target-language speaking experience. VR can provide the opportunity for users to build the skills necessary to carry out a conversation without the fear of social consequences present in the physical world (Rosenfield et al., 2019). Therefore, VR is a promising avenue for improving conversational English skills as a way of dynamically creating believable scenes for conversational training and role-play (Chang et al., 2012). It is hoped that after the research project, the instructors in China will be introduced to this VR technology and they can integrate the technology into classroom instruction and therefore facilitate the teaching and learning of English.

*required

Have there been any specific issues that have been identified that may represent a difference in standard practices between the local IRB and the Purdue University IRB? If so please describe.

We do not recognize any differences between Purdue IRB and the local IRB of China regarding standard practices.

*required

Describe if the researcher was invited into the community. If yes, then provide documentation of the collaboration. If not, describe how the researcher will have culturally appropriate access to the community.

One of our researchers, Weijian Yan, comes from China and will be served as the contact person for the university in China. She will ensure culturally appropriate communication among the research team and the research setting and the participants. A collaboration letter has been provided for China.

*required

Describe any aspects of the cultural, political or economic climate in the country where the research will be conducted which might increase the risks for participants. List the specific risks and how these risks will be minimized.

We do not know any cultural or political issues in China that research would increase any risk for participants.

*required

Please describe how and when the informed consent documents will be translated.

The informed consent for students is already translated. This process was done by a team member whose native language is Chinese. However, students are all proficient enough to translate them from English to their native language, Mandarin.

Upload translated documents prior to the study, when available.

Culturally Appropriate Letter-IRB2023597.pdf

letter of collaboration-IRB2023597.pdf

Translation of Consent Form-IRB2023597.pdf

*required

Please attach a letter from a cultural expert who is not a part of the research team, affirming the cultural appropriateness of the study.

If there is not a local Ethics Committee, investigators must rely on local or experts or community leaders to provide approval and affirm the research procedures are appropriate for the cultural context of the participants.
Culturally Appropriate Letter-IRB2023597.pdf

letter of collaboration-IRB2023597.pdf

Translation of Consent Form-IRB2023597.pdf

Informed Consent Process

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

---

*required

Identify which subjects will consent to participate in the research.

✓ All subjects (or their legally authorized representative) will consent to participate in the research.

Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.

No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

✓ All consented subjects will provide a written signature as documentation of consent

Some subjects will provide a signature as documentation of consent, and some subjects will not.

No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

Yes

✓ No

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

The department administrator to send the recruitment email to the potential participants with the researchers' contact information.

After one week after sending the first email, the department administrator to send the recruitment email to the potential participants again to remind them of the research recruitment and invite students to participate.

If students want to know more about the research or want to participate in the research, they will contact the PI or contact person listed in the email. The deadline to indicate interest is 2 weeks after the initial invitation email.

After two weeks after sending the initial recruitment email, researchers will email a consent form in Microsoft Word form with the PI's signature to the students who agree to participate in the research. Participants can ask any questions about the study, the content forms, or anything else they would like more information about. Participants are requested to sign their names by drawing a signature using a mouse in the Word document and send one copy back to the researchers for file keeping before the end of the third week after they receive the first email.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained

- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting a basic section from the consent form.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*

- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*
- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

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*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.

For purposes of recordkeeping, the HRPP/IRB will need to have a Word or PDF version of any electronic forms. Please include more than a link.

Consent Form-IRB2023597.docx

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms (such as the consent form) when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor. You will list any pending sources in the next question.

If the research is funded by a subcontract, please add both the subcontract source and the prime sponsor.

Researchers are affirming that any intent of the IRB application is congruent with the intent of the funds referenced.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

✓ None - There are no confirmed funding sources at this time.

ANTICIPATED Funding Source(s) - Required

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

✓ There are no pending funding sources at this time.

If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

We plan to submit a grant proposal for funding for future research.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The HRPP/IRB may request confirmation that proper disclosures have been made.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate before proceeding. Principal Investigators must certify all submissions prior to review by the HRPP/IRB.

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*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

You may attach COVID-19 Research Space Standard Operating Procedures here if this is a new protocol submitted during the COVID-19 pandemic.

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

✓ Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

Kaltura Security and Privacy Policy-IRB2023597.pdf

No