Protocol Title: Exploring the Impact of Belonging for Computer Science Education using Virtual Reality Avatars

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* * * Personnel Information * * *

Principal Investigator Mandatory

CSU defines "Investigator" as an individual who conducts a research study. If the study is conducted by a team of individuals, the Investigator is the responsible leader of the team. Students, fellows and residents may not act as a Principal Investigator.

Name of Principal Investigator*		Degree (MD/PhD/BSN/etc.)		Title
Ortega, Francisco		PhD		Assistant Professor
Email*		**Phone**		**Fax**
F.Ortega@colostate.edu		(970) 491-7445		
Research Department		**CSU Status Check ALL that apply***		**Mailing Address**
1873 Computer Science	X	Faculty		
		Staff		
		Other		

ALL research personnel are required to complete Human Subject Research training from CITI within the last 3 years prior to engaging in any research-related activities. Go to CITI Program to complete.

Any NIH funded clinical trials require GCP training.

The Research Compliance Office will verify the last date of completion below.

CITI Training Date*	Type of CITI training completed.*
04/02/2019	Group 2 Social/Behavioral

Training Details

No training data is available.

CO-Principal Investigator

Name of Co-Principal Investigator*		Degree (MD/PhD/BSN/etc.)		Title
Gaddy, Vidya		BS		Graduate Assistant
Email*		**Phone**		**Fax**
Vidya.Gaddy@rams.colostate.edu				
Research Department		**CSU Status Check ALL that apply***		**Mailing Address**
Computer Science		Faculty		
		Staff		
	X	Other	Master student	

ALL research personnel are required to complete Human Subject Research training from CITI within the last 3 years prior to engaging in any research-related activities. Go to CITI Program to complete.

Any NIH funded clinical trials require GCP training.

The Research Compliance Office will verify the last date of completion below.

CITI Training Date	Type of CITI training completed.*

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01/22/2018	Group 2 Social/Behavioral
Training Details	
No training data is available.	

Department Head Mandatory

Name of Department Head*		Degree (MD/PhD/BSN/etc.)		Title
Partridge, Craig				Professor
Email*		**Phone**		**Fax**
Craig.Partridge@colostate.edu				
Research Department	**CSU Status Check ALL that apply***			**Mailing Address**
Computer Science	X	Faculty		
		Staff		
	X	Other	Chair	
ALL research personnel are required to complete Human Subject Research training from CITI within the last 3 years prior to engaging in any research-related activities. Go to CITI Program to complete.				
Any NIH funded clinical trials require GCP training.				
The Research Compliance Office will verify the last date of completion below.				
CITI Training Date			**Type of CITI training completed.***	
			Group 2 Social/Behavioral	
Training Details				
No training data is available.				

Administrative Contact

Name of Administrative Contact*		Degree (MD/PhD/BSN/etc.)		Title
Wolfe, Heather				Accounting Technician III
Email*		**Phone**		**Fax**
Heather.Wolfe@colostate.edu				
Research Department	**CSU Status Check ALL that apply***			**Mailing Address**
Computer Science		Faculty		
	X	Staff		
		Other		
ALL research personnel are required to complete Human Subject Research training from CITI within the last 3 years prior to engaging in any research-related activities. Go to CITI Program to complete.				
Any NIH funded clinical trials require GCP training.				

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The Research Compliance Office will verify the last date of completion below.	
CITI Training Date	Type of CITI training completed.*
	Group 2 Social/Behavioral
Training Details	
No training data is available.	

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* * * Subject Checklist * * *

Subject Checklist

Select All That Apply :

- Children under 18
- Pregnant women
- Fetuses/neonates
- Prisoners
- Military personnel
- X Adult Volunteers
- Economically/educationally disadvantaged
- Individuals with impaired decision-making capacity
- X University students
- University employees
- Illiterate
- Homeless
- Public officials/candidates for public office
- Institutionalized patients/residents
- Persons incompetent to give consent (e.g., dementia, comatose, have legal guardians)
- X Healthy Individuals

Other (please specify):

---

* * * Study Location * * *

Study Location

Select All That Apply - NOTE: Check "Other" and input text: 1.) If your study location is not listed, or 2.) If you would like to list details of your already-checked location (e.g., specific school within a school district)

- X Colorado State University
- Colorado State University - Pueblo
- University of Colorado Health
- University of Colorado Boulder
- University of Colorado - Colorado Springs

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University of Colorado Denver
Other University/College
Other Medical/Health Care Facility
School/School District
Other (please specify)

Has this protocol been submitted to any other Institutional Review Board not listed above? N

Is this a multi-site project? (A multi-site study is one where different PIs at different institutions are conducting the same study or aspects of the same study.) N

Will Colorado State University function as the coordinating center or lead institution? Y

(Please submit an IRB approval or Letter of Permission/Support from other locations, if applicable, and for any site not under the jurisdiction of the CSU IRBs.)

---

* * * General Checklist * * *

General Checklist

Select All That Apply :

Request to Rely on Another IRB - Please upload completed Request to Rely and associated documents in attachment section

IRB Authorization Agreement (IAA), Memorandum Of Understanding (MOU), etc.(attach in the Attachments section (This only applies to studies where the Client IRB is the Reviewing IRB).

Industry-Sponsored Clinical Trial

X Interview

X Questionnaire/Survey

Thesis or Dissertation Project (Please upload proposal and dissertation/thesis committee approval in Attachments section.)

Radioisotopes/radiation-producing machines, even if standard of care (Radiation Safety)

Human blood, cells, tissues, or body fluids (Institutional BioSafety)

Tissues to be stored for future research projects

Tissues to be sent out of this institution as part of a research agreement (Material TransferAgreement (MTA))

Human Embryos

Human Embryonic Cells? Provide NIH Code Number(s) or state that no federal funding will be used to support this research.

Use of Patient related equipment? If Yes, specify what equipment is being used.

Medical equipment used for human patients/subjects also used on animals.

Protocol involves studying potentially addicting drugs.

Investigational drugs, reagents, or chemicals

Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)

Investigational Device

This study involves drugs or devices regulated by FDA

Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Tissues (e.g., blood, cells, body fluids).

This study is or will be posted on ClinicalTrials.gov

If checked, Specify number:

Protected Health Information (PHI) will be viewed, created, accessed, used, or disclosed.

HIPAA Authorization

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Waiver or Alteration of Authorization

Activities Preparatory to Research

Limited Data Set and Data Use Agreement

Use and Disclosure of Decedents PHI without Authorization

Class Project

X Other (clarify in text box to the right)

Virtual reality headset used for virtual environment simulation

---

* * * Funding * * *

X NONE--This project does not have any funding. If you want to add Funding for the study, please uncheck "NONE."

Funding

Add external and internal grant funding source(s) below: Federal Government, Other Gov. (i.e., State, local), Foundation or Other. Select "None" above if there is no external funding for the study.

It is CSU Policy to review grant applications with IRB submissions for congruency. Upload your grant in the attachment section.

Funding for this study was secured by the Office of Sponsored Programs

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* * * Application Type Checklist * * *

Application type checklist

Not Human Subjects Research

X Exempt

Expedited/Full Board

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* * * Exempt Paragraphs(s) * * *

There are eight categories of research activities involving human subjects that may be exempt from the requirements of the Federal Policy for the Protection of Human Subjects (45 CFR 46). Select from the following applicable categories to determine if your research is exempt from expedited or full committee review. If your research qualifies under one or more of the exempt categories, proceed with the following application. If not, complete the expedited or full review application.

NOTE: The exempt categories below do not apply to research involving prisoners. For research subject to Subpart C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects), the Final Rule changed the pre-2018 rule to allow the exemptions to apply to Subpart C for "research involving a broader subject population if the research only incidentally includes prisoners" (HHS 2017).

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Secondary research (using the information or biospecimens) with subjects who are prisoners is allowed by the Final Rule if the research is not seeking to examine prisoners as a subpopulation. The Final Rule allows subjects to continue in exempt research if they become prisoners during a study.

Select one or more of the following paragraphs applicable to your project:

1. **EDUCATIONAL PRACTICES: Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact student's opportunity to learn required educational content of the assessment of educators who provide instruction. This includes most:**
   - i. Research on regular and special education instructional strategies; OR
   - ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

   This category does not apply to use of school records of identifiable students or interviewing instructors about specific students.

2. **EDUCATIONAL TESTS (COGNITIVE, DIAGNOSTIC, APTITUDE, ACHIEVEMENT), SURVEY PROCEDURES, INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR (INCLUDING VISUAL OR AUDITORY RECORDING): Research involving these procedures is exempt, IF one of the following is correct:**
   - i. Any information obtained is recorded in such a manner that subjects CANNOT be identified, directly or through identifiers linked to the subjects; OR
   - ii. Any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, educational advancement, or reputation; OR
   - iii. Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects CAN readily be identified, directly or through identifiers linked to the subjects, AND an IRB conducts a Limited IRB review to make the determination required by 45 CFR 46.111(a)(7) and the research is not subject to 45 CFR 46 Subpart D.

   This exemption does not apply to children except for research involving observation of public behavior when the investigator does not interact with the children. Workplace meetings and activities, as well as classroom activities, are not considered "public behavior".

X 3. **RESEARCH INVOLVING BENIGN BEHAVIORAL INTERVENTIONS in conjunction with the collection of information from adult subjects through verbal or written response (including data entry) or audiovisualrecording, if the subject prospective agrees to the intervention and information collection,is exempt, IF**
   - i. Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be identified, directly or through identifiers linked to the subjects, OR
   - ii. Any disclosure of the subject's responses outside of the research could NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; OR
   - iii. Any information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be identified, directly or through identifiers linked to the subjects, and an IRB conducts a Limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

4. **EXISTING DATA: Secondary Research involving collection or study of existing data, documents, records, or biospecimens, for which consent is not required is exempt, IF:**
   - i. The identifiable private information or identifiable biospecimens are publicly available; OR
   - ii. Information, which may include information about biospecimens, is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify the subjects; OR
   - iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subpart A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 1.512(b); OR
   - iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable

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private information that is or will be maintained on information technology that is subject to and in compliance with section 298(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 5521, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501et seq.

5. **RESEARCH AND DEMONSTRATION PROJECTS CONDUCTED BY OR SUBJECT TO THE APPROVAL OF DEPARTMENT OR AGENCY HEADS:This research is exempt IF it is designed to study, evaluate, or otherwise examine:**

   i. Public benefit or service programs;

   ii. Procedures for obtaining benefits or services under those programs;OR

   iii. Possible changes in or alternatives to those programs, OR

   iv. Changes in methods or levels of payment for benefits or services under those programs.

   Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts of consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 115A of the Social Security Act, as amended.

   Note:Each Federal department or agency conducting or supporting research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. **TASTE AND FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES: This research is exempt, IF:**

   i. Wholesome foods without additives are consumed; OR

   ii. A food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture (USDA); OR

   iii. A food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the FSIS of the USDA

7. **STORAGE OR MAINTENANCE OF INFORMATION FOR SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED: The protocol is eligible for exemption if:**

   i. It involves storage or maintenance of identifiable private information or identifiable biospecimens for secondary research use; AND

   ii. All the identifiable information or identifiable biospecimens that are to be stored and/or maintained for secondary research have been or will be collected for another "primary" purpose; AND

   iii. Broad consent for the storage or maintenance of their identifiable information or identifiable biospecimens for secondary research use will be obtained from ALL subjects; AND

   iv. The protocol does not include any activities that do not qualify for exemption; AND

   v. The protocol is not for an FDA regulated clinical investigation; AND

   vi. The IRB conducts a Limited IRB Review and makes the determinations required by 45 CFR 46.111(a)(8)

8. **SECONDARY RESEARCH FOR WHICH BROAD CONSENT IS REQUIRED: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use is eligible for exemption, if the following criteria are met:**

   i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d); AND

   ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; AND

   iii. An IRB conducts a Limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; AND

   iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

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* * * Summary, Purpose, Procedures * * *

Title (Please indicate if the protocol title is different from the proposal title)

Exploring the Impact of Belonging for Computer Science Education using Virtual Reality Avatars

Proposed Start Date: 01/27/2020 **Proposed End Date:** 01/27/2021

1. Summary

a) Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

The project will have participants use an Oculus Rift S Virtual Reality head set to immerse themselves in a simple simulated environment. Within the simulated environment they will listen to an audio recording and verbally answer a question posed by the audio recording. Once they have answered the question they will remove the head set and fill out a short survey on their experience and their background in computer science.

2. Purpose

a) Describe the purpose for the proposed project as well as the hypotheses/research questions to be examined.

The purpose of the project is to determine if a family background or personal connection with computer science (CS) is a deciding factor when choosing to take part in a computer science course.
Research Questions:
(1) Does a familial background or personal connection with CS and the technology community (a sense of belonging) influence a student's decision to take CS courses?
(2) Can a virtual environment influence a person's sense of belonging in CS enough to affect their decision to take a CS course?
Hypotheses:
(1) Participants without an initial sense of belonging (henceforth, Pw/oB) primed with audio cues in a virtual environment meant to encourage a sense of belonging (positive cues) will be more likely to enroll in a hypothetical CS course than Pw/oB who are primed with audio cues in a virtual environment meant to discourage a sense of belonging (negative cues).
(2) Participants with an initial sense of belonging (PwB) primed with positive cues will be more likely to enroll in a hypothetical CS course than Pw/oB who are primed with positive cues.
(3) PwB primed with positive cues will be more likely to enroll in a hypothetical CS course than PwB who are primed with negative cues.
(4) PwB primed with negative cues are more likely to enroll in a hypothetical CS course than Pw/oB primed with negative cues.

b) What do the investigators hope to learn from this project?

The project will provide insight as to how effective virtual reality is when being used to influence a persons sense of belonging. And the project will provide insight into the relationship between familial background and enrollment in computer science courses.

c) Please share your plans to share the results of this study with intentions to influence behavior,practice, theory, future research designs.

I plan to publish the results of this study at conferences for both computer science education and virtual reality. The intent of the research is to be a starting point for improving the sense of belonging despite a lack of family background.

3. Procedures

a) Describe in chronological order of event(s) how the activities will be conducted, providing information about all procedures (e.g. interventions/interactions with subjects, data collection, photographing, audio and video recording), including follow up procedures.

I will send out a request to the student body of my institution for participation in the study. Initially I will ask students within my department through email correspondence.

As I collect a sufficient number of participants I will schedule a date and time with each individual where they can meet me in my lab (NuiLab.org) in the computer science department building at my university.

I will set the participant up at my desk and give a brief description of what they will be doing as well as have them sign a consent form (See introductory_script.pdf & consent_form.pdf). I will discuss how virtual reality works, that they will be in a simulation playing as an avatar and listening to an audio recording. I will also instruct them to answer the question posed by the audio recording verbally. I will give them a short description of the avatar they will embody, specifically telling the participant that the avatar has never taken a

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give them a short description of the avatar they will embody, specifically telling the participant that the avatar has never taken a computer science course before.

The participant will then put on the head set and go through the simulation listening to a voicemail of the secondary investigator's creation that will prompt them to believe they either have a family background in computer science or that they don't. The audio clip will then ask them if they would like to take a computer science course. They would then respond verbally to me which I will manually record. They can then remove the head set.

I would then like them to fill out a short four question Google forms survey asking the participant to provide non-identifying information about their personal and family background in computer science as well as a question about the degree to which they felt connected to the avatar.

To conclude the experiment we will de-brief the participant about the purpose and goal of the experiment.

i) **Be sure to identify what procedures are experimental and what are standard of care or established practice for the condition/situation.**

The participant taking part in the simulation, answering the question posed by the audio recording, and completing the survey are the experimental aspects of the study. Collecting participants, getting consent, and experimental disclosure are standards of care.

b) **Explain who will conduct the procedures and where and when they will take place. Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study. Include how the data will be collected (i.e. in person or online).**

Dr. Francisco Ortega, the Principal Project Investigator, has conducted multiple experiments. His expertise are in Human-Computer Interaction, 3D User Interfaces, and VR/AR modalities

All investigators have completed CITI Training and their certificates are attached to the application.

The procedures will be conducted during the months of January 2020 through January 2021 in the computer science building at Colorado State University.

The experimental session will last approximately 5 to 10 minutes.

The data will be collected via Google Forms, Google Sheets and in person.

i) **Indicate that the instruments used are in the public domain or provide appropriate documentation of permission to use each scale.**

We will be using technology in the public domain, including an Oculus Rift S, an alienware desktop, and online services.

c) **For school-based activities where class time is used, describe in detail the activities planned for non-subjects and explain where both subjects and nonsubjects will be located during the activities.**

N/A

d) **State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in attachments section**

Deception will not be used in this study.

e) **Will audio or video taping of individuals occur? Will photographs of individuals be taken? Describe what will become of the apes/photographs (e.g., shown at scientific meetings, erased, etc.).**

No photos, audio or video taping of participants will occur.

f) **Will the proposed research involve the use of existing data/specimens? (This is mandatory at this time, please select any regardless of applicability until corrected.)**

- [ ] **i. The research involves data from publicly available sources**
- [X] **ii. That data will be recorded by the investigator in such a manner that subjects cannot be identified.**
- [X] **iii. Any link to identifying information has been destroyed**

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If YES to any of these for the whole of your research activities, please contact RICRO_IRB@mail.colostate.edu for guidance on submitting the Exempt Application or Expedited/Full or review exempt categories at: https://vpr.colostate.edu/ricro/irb/submit-a-protocol/

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* * * Background and additional procedures * * *

4. Background and additional procedures

a. Relevant Background: Discuss the present knowledge, appropriate literature and rationale for conducting the research. Include the rationale for the selected subject population.

There has been a persistent decline in the number of diverse students entering computer science (CS) and technological majors for several decades. (Tracy Camp. 2012. 'Computing, we have a problem …'. 2012. ACM Inroads 3, 4. 34-40. DOI: https://doi.org/10.1145/2381083.2381097) This decline has resulted in lower rates of employment in STEM fields (especially technology fields) for diverse populations during a time when there is an excess of technology-related careers to go around in this country. (U.S. Department of Labor Bureau of Labor Statistics. 2018. Occupational Outlook Handbook, Computer and Information Technology Occupations. www.bls.gov, Liana Christin Landivar. 2013. Disparities in STEM employment by sex, race, and Hispanic origin. 2013. Education Review 29, 6. 911–922.) There is plenty of evidence to suggest that diversity is a major contributor to innovation and a variety of backgrounds are crucial when developing new ideas. (David Rock and Heidi Grant. Why diverse teams are smarter. 2016. Harvard Business Review 4, 4. 2–5., Inga J Hoever, Daan Van Knippenberg, Wendy P Van Ginkel, and Harry G Barkema. Fostering team creativity: perspective taking as key to unlocking diversity's potential. 2012. Journal of applied psychology 97, 5. 982.) Therefore solving the problem of underrepresentation is pivotal in the coming years as new innovative technologies become necessary to combat society's ever-growing challenges.
Before diversity can spread within technological industries the reasons behind the decline must be explored and properly dealt with. The research I am pursuing is a unique avenue toward the goal of solving the underrepresentation problem in CS and other technological fields. There is evidence to suggest that there is a lack of belonging among diverse minorites in CS. (Colleen Lewis, Paul Bruno, Jonathan Raygoza, and Julia Wang. 2019. Alignment of Goals and Perceptions of Computing Predicts Students' Sense of Belonging in Computing. In Proceedings of the 2019 ACM Conference on International Computing Education Research (ICER '19). ACM, New York, NY, USA, 11-19. DOI: https://doi.org/10.1145/3291279.3339426) This study will be exploring where that lack of belonging stems from. The experiment will indicate to what degree a lack of belonging influences a persons willingness to participate in CS courses. And the experiment will explore potential methods of influencing a persons sense of belonging.
The various participants will provide useful data. The participants in CS will provide data on the effectiveness of the simulation to influence enrollment. And the participants who are not in CS will provide data on the effect of background on enrollment.

b. Do any of the following apply.

i.	Will subjects be audio recorded?	N
ii.	Will subjects be videotaped?	N
iii.	Will subjects be photographed?	N

If yes to i, ii or iii, explain the collection process and use in the context of this research of such media

(Explicit consent must be obtained for use of these methods for Expedited and Full Board studies.)

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* * * Subject Population (a-f) * * *

5. Subject Population

a) How many subjects to you intend to enroll and/or how many subject records to you intend to access?

i. At this site

# of subjects	80
# of records	0

ii. At all sites — N/A

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# of subjects

# of records

b) **Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.)**

i. **Identify inclusion criteria.**

Must be a student enrolled at a university or college

ii. **Identify exclusion criteria.**

N/A

c) **What is the rationale for studying the requested group(s) of participants?**

Participants will reflect the target population of interest: Students in technology fields, students who have not yet chosen a field of study, and students who have chosen not to pursue technology fields.

d) **State if any of the subjects are students, employees, or laboratory personnel. Please explain how subjects will be protected from coercion and undue influence** N/A

e) **Please describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, and training). Also, explain your knowledge of local community attitudes and cultural norms and cultural sensitivities necessary to carry out the research (e.g., differences with U.S. culture).**

Dr. Fransisco Ortega is a human-computer interaction expert. He has his Ph.D. in Computer Science and he has been conducting experiments for 9 years.
The other investigator has spent their life in this location which has resulted in a deep understanding of the population. She has a B.S. in Computer Scienc with a concentration in human-centered computing.

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* * * Subject Population (g-j) * * *

5. Subject Population

f) **Will bilingual or multilingual subjects be recruited?** N

g) **Will non-English speaking subjects be recruited?** N

If yes, state language(s) spoken (other than English):

h) **Will subjects be less than 18 years of age?** N

i) **Describe any planned screening procedures. Attach your screening document(s) (e.g., health history questionnaire) in the Attachment Section (#16).**

---

* * * Recruitment Process, Subject Compensation and Costs * * *

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6. Recruitment Process:

a) Describe the step-by-step procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials.

- **List any specific agencies or institutions that will provide access to prospective subjects.**
- **Identify who will contact prospective subjects and how.**

Collecting Participants:
1. Word of mouth - primary and secondary investigators
2. Announcements in classes with permission from professors - primary and secondary investigators
3. Department forwarded solicitation requests through email - distributed by Fransisco Ortega
Data requests:
Link sent to survey to be taken in the presence of investigator through email or other related digital means

b) Planned Subject Identification Methods:

	N/A	X	Direct advertising
	Chart/database review		Living conditions (e.g., nursing home residents)
	Class participants		From PI's own practice/clinic/class
	Circumstance (e.g., homelessness)		Referrals
	Organization mailing lists		CSU Subject Pool
	Other (please specify):		

c) Planned Recruitment Materials/Methods:

	N/A		Flyers/posters
	Phone Scripts		Letters to providers/schools/organizations
	Television ads		Newspaper ads
	Letters to prospective subjects		Radio ads
	Oral Scripts		PowerPoint presentations
X	Internet ads/postings	X	Email
X	Face to face interactions	X	CSU Subject Pool
	Other (please specify):		

(All advertising must be submitted for review in its final printed/recorded form)

Note: Attach copies of ALL recruitment materials in the attachment Section

7. Subject Compensation and Costs:

a) Will subjects receive compensation for participation? N

Total amount (in dollars or equivalent)

b) Form of Compensation:

	Cash		Raffles/lotteries
	Check		Course/extra credit
	Gift card/certificate		Reimbursement only
	Voucher		Other (please specify)

c) Describe the remuneration plan (Include when subjects will be paid, whether payment will be prorated and whether a 1099 will be issued.)

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NA

d) For raffles include the number of prizes, nature and value of each prize.If possible, include odds of winning.

NA

e) If extra course credit is offered be sure to address the alternative means by which students can accrue extra course credit should they not wish to participate in the study.

NA

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* * * Risks * * *

8. Risks (Input N/A if not applicable)

US Department of Health & Human Services (HHS) Regulations define a subject at risk as follows: "...any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

X Minimal Risk: probability and magnitude are not greater than everyday living OR are encountered in daily or routine medical, dental or psychological exams

b) Describe all known risks or discomforts associated with study procedures.

1) Physical well-being

There is a slight risk of motion sickness when using virtual reality devices. There will be no cause for the participant to move in the simulation, and they will be encouraged not to in order to mitigate the risk of motion sickness.
If any signs of motion sickness do occur the participant will be immediately removed from the virtual reality headset.

2) Psychological well-being

The risk to psychological well-being is minimal since the participant is expected to identify with but not personify the avatar in the simulation. The risk of affecting the participants' own sense of belonging in computer science is mitigated by the short duration of the simulation as well.

3) Economic well-being

There is no economic risk foreseen in this experiment

4) Social well-being

No data will include personally identifying information, and it will be secured behind a password protected computer to prevent any social risk.

c) Describe the procedures or safeguards in place to protect against or minimize potential risks (e.g., referral to psychological counseling resources).

The participants will be reminded verbally that they can stop the experiment at any time.

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* * * Benefits * * *

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9. Benefits

a) Discuss any potential benefits that would justify involvement of subjects in this study.

i. Direct benefits to subjects (if applicable)

ii. Indirect benefits to society

b) Explain how the potential benefits justify the potential risks involved in participation in this research.

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* * * Procedures to Maintain Confidentiality * * *

10. Procedures to Maintain Confidentiality

Which of the following types of data will you work with:

Identifiable Information is considered to be identifiable when it can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems, or when characteristics of the information obtained are such that by their nature a reasonably knowledgeable person or investigator could ascertain the identities of individuals. Therefore, even though a dataset may have been stripped of direct identifiers (names, addresses, student ID numbers, etc.), it may still be possible to identify an individual through a combination of other characteristics (e.g., age, gender, ethnicity, and place of employment).

Anonymous Data are anonymous if no one, not even the researcher, can connect the data to the person who provided it--no identifying information is collected from the individual. Investigators must be aware, however, that even if no direct identifiers (name, address, student ID, etc.) are collected, identification of a participant may be possible from unique individual characteristics (indirect identifiers). For example, a participant who is a member of a certain ethnic group or who was studied because of distinctive personal accomplishments or medical history might be identifiable from even a large data pool.

X De-identified If the dataset has been stripped of all identifying information and there is no way that it could be linked back to the subjects from whom it was originally collected (through a key to a coding system or by any other means). Note: This also applies if the source of the data is identifiable but the data collected is not.

Coded This refers to data that have been stripped of all direct subject identifiers, but in this case each record has its own study ID or code, which is linked to identifiable information such as name or medical record number. The linking file must be separate from the coded data set. This linking file may be held by someone on the study team (e.g. the PI) or it could be held by someone outside of the study team (e.g. researcher at another institution). A coded data set may include limited identifiers under HIPAA. Of note, the code itself may not contain identifiers such as subject initials or medical record number.

a) If information derived from the study will be provided to the subject's personal physician, a government agency, or any other person or group (other than the research team), describe to whom the information will be given and the nature of the information, if applicable. N/A

b) Explain how you will protect subjects' privacy. Note: Privacy refers to persons and their interest in controlling the access of others to themselves. For example, based on their privacy interest's people want to control:

- The time and place where they give information.
- The nature of the information they give.
- The nature of the experiences that are given to them.
- Who receives and can use the information.

For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy-counseling center

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that is clearly identified as such by signs on the front of the building. Please keep this definition in mind as you respond to this item.

All experiments will occur in the NUI lab at Colorado State University between 8am and 5pm. The identifying information on consent forms will be removed. The results of this study may be used in reports, presentations, and publications; but the researcher will not identify participants individually in such publications.

c) **Describe how you will maintain the confidentiality of subjects' information. Note: Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others (without permission) in ways that are inconsistent with the understanding of the original disclosure. Please keep this definition in mind as you respond to this item.**

Consent forms will be placed in a locked filing cabinet and unmoved for the duration of the experiment. The only way to identify the subject based on their survey responses is based on the timestamp of when they completed the survey. The data from the experiment and survey will be locked behind a password protected account and destroyed after analysis.

d) **Who will have access to study records or specimens? (Please identify specific team members by name.)**

Dr. Francisco Ortega and Vidya Gaddy

e) **If you plan to use existing data, records or specimens, what is the source of the data/records/specimens, and how will you access them?NOTE: "Existing" means data or specimens collected (i.e., on the shelf) prior to the IRB application submission. It includes data or specimens collected for research and non-research activities.**

NA

f) **How will subjects be asked to provide their permission for release of identifiable data collected as a part of this proposed research (e.g., pictures, recordings, responses to research questions), now or in future? Explain and include appropriate statements in consent materials.**

Each participant will be asked to read the consent form for the study. The consent form will include any potential risks and it will provide a basic description of what the participant will be doing. The participant will have a chance to ask any questions they have about the experiment which the researcher will answer, then they will be asked to sign the consent form.

g) **If using existing data/biological specimens, will the researchers have access to a code linking the data to personally identifiable information?**

NA

h) **If the data is coded, explain where the key to identifiers will be stored, how it will be protected, and who will have access to it.**

NA

i) **Explain why, where, in what format, and for how long data/specimens will be retained.**

Data will be retained for analysis behind a password protected student account in a spreadsheet accessible only through a password in the Computer Science building at Colorado State University. The data will be deleted once the data has been analyzed and research paper written.

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* * * Consent Information * * *

11. Consent Information

11 a & b only apply to exempt applications

a) **How will subjects be informed of procedures, intent of the study, and potential risks to them?**

Each participant will be asked to read the consent form for the study. The consent form will include any potential risks and it will provide a basic description of what the participant will be doing. The participant will have a chance to ask any questions they have about the experiment which the researcher will answer, then they will be asked to sign the consent form.

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b) **How will subjects be informed they may withdraw at any timewithout penalty?**

Verbally prior to the experiment and in writing on the consent form

Note: Attach, in the Attachments Section, written and/or verbal instructions the subject will receive.

See sample consent forms at https://vpr.colostate.edu/ricro/irb/templates/

Please provide consent process background information below.

---

* * * Assent Background * * *

12. Assent Background

(Complete if applicable)

Assent Document: A form or script of the information that will be conveyed to the child about the study. In general, researcher must obtain the affirmative agreement of children ages seven years and older for their participation. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of hildren, more than one assent form may be needed (i.e., an assent from suitable for a 17 year old is not usually suitable for a 7 year old child).

Assent Waiver: No child assent will be sought at all. This means that the IRB is asked to waive the requirement for child assent. Among other circumstances, this option is appropriate when the capability of the child to understand the research is too limited or when the research holds out a prospect of direct benefits that is important to the health or well-being of the child.

All minors must provide an affirmative consent to participate by signing a simplified assent form, unless the Investigator(s) provides evidence to the IRB that the minor subjects are not capable of assenting because of age, maturity, psychological state, or other factors.

See sample consent/assent forms at https://vpr.colostate.edu/ricro/irb/templates/

Provide assent process background information, in the space below, for each Assent Form, Alteration Form (i.e., Cover Letter or Verbal Script), and Waiver.

---

* * * HIPAA * * *

13. Health Insurance Portability and Accountability Act (HIPAA)

If you are using PHI and this page is not active you must return to the General Checklist and check the box regarding the use of PHI in this research.

The HIPAA Privacy Rule establishes the right of an individual to authorize a covered entity, such as health plan, health care clearinghouse or health care provider, to use and disclose his/her Protected Health Information (PHI) for research purposes.

The Privacy Rule defines the elements of individual information that comprise PHI and establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. It also includes provisions to allow an individual's PHI to be disclosed or used in research without the person's authorization (i.e., IRB Waiver of HIPAA Requirement Authorization).

Is Your Research Covered by HIPAA's Privacy Rule?

Protected Health Information (PHI) is health information with one or more of the following identifiers. For more information see: http://privacyruleandresearch.nih.gov/clin_research.asp or consult HIPAA Privacy Rule for Research

Research which involves the use of de-identified data is exempt from HIPAA requirements. In order to be de-identified data. NONE of the subject identifiers listed below can be collected, used, reviewed, recoded, accessed or disclosed.

Please review the following list and indicate if any of the information will be collected from any medical records for the purpose of this research project.

1. Names

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2. Social Security Numbers
3. Telephone Numbers
4. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census;
   i. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
   ii. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
5. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all wages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
6. Fax Numbers
7. Electronic Mail Addresses
8. Medical Record Numbers
   - You must attach a data collection sheet identifying the data points being collected from the MRN
9. Health Plan Beneficiary Numbers
10. Account Numbers
11. Certificate/License Numbers
12. Vehicle Identifiers and Serial Numbers, including License Plate Numbers
13. Device Identifiers and Serial Numbers
14. Web Universal Resource Locations (URLs)
15. Internet Protocol (IP) Address Numbers
16. Biometric Identifiers, including Finger and Voice Prints
17. Full Face Photographic Images and any Comparable Images
18. Any other unique identifying number, character, or code (note this does not mean the unique code assigned by the Investigator(s) to code the research data)

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* * * Potential Conflict of Interest * * *

15. Potential Conflict of Interest

Conflict of Interest and the definitions related to the Conflict of Interest Policy and the following questions, please refer to the Help Screen.

Conflict of Interest: Please check Yes or No for each item below.

a) Does the research involve a drug, device, or biological invented by you, an immediate family member or other Research Personnel?

b) Is the research sponsored by an entity with which you, an immediate family member, or other Research Personnel have a paid consulting or advising relationship?

c) Will you, members of your immediate family, or other Research Personnel receive special compensation or increased compensation if the research generates a favorable outcome?

d) Will you, members of your immediate family, or other Research Personnel receive any money, gift or anything of monetary value above and beyond the actual costs of enrollment, conduct of the research, and reporting on the results, including, but not limited to, finders fees, referral fees, recruitment bonuses, and an enrollment bonus for reaching an accrual goal or similar types of payments?

e) Do you, members of your immediate family or other Research Personnel have any other interests or relationships (including volunteer services) that might constitute a conflict of interest or an appearance of conflict of interest in connection with the research project?

f) Will the payment you receive for services provided during the conduct of the research (e.g., investigator and Research Personnel time and tests) be inconsistent with fair market value for those services?

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Significant Financial Interest: Please check Yes or No for each item below.

g) Will you, your immediate family members or other Research Personnel receive salaries, royalties and/or other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership seminars, lectures or teaching engagements when totaled together exceeded $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months)? This excludes reasonable costs of conducting the research, as specified in the research agreement.

h) Do you, your immediate family members, or other Research Personnel hold any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in the sponsoring organization? This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the investigator and/or his or her immediate family do not exercise day-to-day control of investment decisions.

Minimizing Risks and Disclosure to Subjects

i) Have you disclosed any actual, potential or perceived conflicts of interest in the consent form? Research Personnel are required to disclose all such conflicts to all research participants in the research consent form.

j) **What steps, if any, have you taken or will you take to manage the conflict of interest and minimize the risks associated with any actual, potential or perceived conflicts of interest arising out of this research?**

If you checked Yes to any statement (a-h, except f) above, please identify the research team member(s) below and provide details concerning the potential conflict of interest.

By submitting this form, you are attesting that you have read the Client HRPP Policy on Conflict of Interest and agree to abide by its terms. You will update this disclosure form when new or changes in conflict of interest arise, and that you will comply with any conflict management plan required by the Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

Link to Client's Conflict of Interest Policy: https://vpr.colostate.edu/ricro/coi/.

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* * * Attachments * * *

16. Attachments

Attach relevant documents here. These could include:

- **Collaborating Investigator's IRB approval and approved documents**
- **Conflict of Interest information**
- **Debriefing Script; Grant/Sub-contract**
- **HIPAA Authorization Form from HIPAA-covered entity**
- **Interview/Focus Group Questions**
- **Investigator's Brochure**
- **Letters of Agreement/Cooperation from organizations who will help with recruitment**
- **Methodology section of associated Thesis or Dissertation project**
- **Questionnaires**
- **Radiation Control Office approval material**
- **Recruitment Material (e.g., flyers, email text, verbal scripts)**
- **Sponsor's Protocol; Surveys**
- **Other files associated with the protocol (you can upload most standard file formats: xls, pdf, jpg, tif, etc.)**

Please be sure to attach all documents associated with your protocol. Failure to attach the files associated with the protocol may result in this

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protocol being returned to you for completion prior to being reviewed.

Students: Be sure to attach the Methods section of your thesis or dissertation proposal. If this protocol is associated with a grant proposal, please remember to attach your grant.

To update or revise any attachments, please delete the existing attachment and upload the revised document to replace it.

Document Type	Document Name	Attached Date	Submitted Date
Questionnaire/Survey	Post Simulation Survey - Google Forms	12/10/2019	
Letters of Agreement.Cooperation	consent_form	12/10/2019	
Other Protocol Material	experiment_script	12/10/2019	

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* * * Obligations * * *

Obligations

The Principal Investigator is ultimately responsible for the conduct of this project.

Obligations of the Principal Investigator include the following:

Provide all subjects a copy of the signed consent form, if applicable.

Modifications - Changes in any aspect of the study (for example, project design, procedures, consent forms, advertising materials, additional key personnel or subject population) will be submitted to the IRB for approval before instituting the changes.

Training - Human subject training certificates, including those for any newly added personnel, will be provided for all key personnel.Training must be updated every three (3) years.

Final Report - The IRB will be notified when the study is complete.

I certify that I have reviewed this application, including attachments and that all information contained herein is accurate to the best of my knowledge. I agree to report any substantive changes to the information contained in this application immediately to the CSU IRB.

I agree to not enroll any subjects or collect any data intended only for research use prior to issuance of an IRB approval.

I agree to manage and maintain all of my research records, including consent retention, for at least three (3) after the close of this study or longer per sponsor requirement.

I understand that I am fully responsible for the execution and management of this study and that I am responsible for the performance of any subinvestigators or key personnel including their adherence to all of the applicable policies and regulations.

This study will not begin until the investigator receives written final approval or determination of exemption.

X **The Principal Investigator has read and agrees to abide by the above obligations.**

Submit the Continuing Review Form in order to maintain active status of the approved protocol. This form must be submitted to the IRB prior to the date of expiration.

Submit the Protocol Violation Form to report protocol Deviations/Violations or the Event Reporting Form to report Adverse Events (AEs) or Unanticipated Problems that occur in the course of the protocol.

X **The Principal Investigator has read and agrees to abide by the above obligations.**

Please click "Check for Completeness" to your left to continue to the next step. If the protocol is complete and ready for submission, please click "Submit Form" to your left to submit your protocol for IRB Review.

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* * * Event History * * *

Event History

Date	Status	View Attachments	Letters
11/15/2019	NEW FORM CREATED		