**INSTRUCTIONS:**

* *Use this “TEMPLATE PROTOCOL (HRP-503)” to prepare a study protocol outlining your research plan.*
* *Depending on the nature of your study, some major sections might not be applicable to your research. If so, simply mark as “N/A.” For example, a simple survey might have many sections with “N/A.” For subsections (e.g., 1.x or 8.x) you can mark as “N/A”if you are certain that the subsection is not applicable.*
* *Once the IRB/HRPP approves your submission, your latest approved version of the protocol will be stored in the IRB Protocol Management online system.*
* *If your research plan changes and you need to modify the protocol, please submit an amendment to Protocol Management with the requested modifications. Download your current protocol from Protocol Management and indicate the changes/revisions using the track changes feature in order to make review of the modifications easier to follow. If you are unable to use track changes, please create a new paragraph wherever you need to make a change, and indicate “Amendment: Date” before making a change to any section. Protocol management will store the older versions of your protocol if the IRB or HRPP staff need to compare them during the review.*

**PROTOCOL TITLE:**

*Include the full protocol title*.

Object Reference in Collaborative Augmented Reality

**PROTOCOL NUMBER:**

*Include the number assigned in Protocol Management (verify this has been added before submitting protocol to HRPP)*.

19-519

**PRINCIPAL INVESTIGATOR:**

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*Telephone Number*: (540) 231-4857

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**FUNDING:**

*Sponsor(s)*: N/A

*Funded already or in the proposal phase?*: Click here to provide a response.

*Is Virginia Tech the primary awardee or the coordinating center of this grant or contract? If not, list the primary institution*: Click here to provide a response.

**VERSION NUMBER/DATE:**

*Include the version number and date of this protocol. Versions should start at 1.0.*

Version 1.0 / 5/22/19

**REVISION HISTORY:**

*Use this table to keep track of changes.**Add more rows as needed.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Brief Summary of Changes  (i.e., the different sections)** | **Consent Change?** |
| 1.0 | 6/2/2019 | The initial submission |  |
| 2.0 | 7/4/2019 | Revision after first submission |  |
|  |  |  |  |
|  |  |  |  |

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# Study Summary

|  |  |
| --- | --- |
| **Study Title** | Object Reference in Collaborative Augmented Reality |
| **Study Design** | The participants will perform multiple collaborative interaction tasks comparing hand referencing of objects in real world and Augmented Reality (AR) setup. We will record participants performance in terms of accuracy and task completion time, as well as qualitative feedback. The data will be analyzed with linear regression to determine the effect of predict factors on task performance |
| **Primary Objective** | We hope to understand more about the characteristics of object referencing in collaborative AR and reveal factors that affect usability of hand referencing interfaces for collaboration in AR. |
| **Secondary Objective(s)** | We could potentially observe difference in object referencing approach between real world and AR collaborations.  We could understand the causality of object referencing difference in physical world and AR |
| **Study Population** | AR Users in general |
| **Sample Size** | 60 |
| **Research Intervention(s)/ Investigational Agent(s)** | surveys, interviews, observations, collecting performance data |
| **Study Duration for Individual Participants** | 60 minutes |
| **Acronyms and Definitions** | AR: Augmented Reality  UI: User Interface |

# Objectives

* 1. *Describe the purpose, specific aims, or objectives of this study*:

When completing a collaborative task, either in the real world or in a virtual environment, it is often needed for a user to draw the attention of their collaborator to a specific object or position. A common approach is to point at the target with a finger or a hand. However, it is unclear how the difference between AR and the real world affects the object referencing performance and how to design AR UI for the best effective result. In this study, we will evaluate user performance with various interaction techniques of object referencing for collaboration in an AR system in a physical environment.

* 1. *State the hypotheses to be tested*:

We hypothesize that users will have different performance in object hand reference for collaboration in AR from the real world.

We hypothesize that different spatial relations between collaborators will affect collaborative performance.

# Background

* 1. *Summarize the relevant prior research on this topic and gaps in current knowledge within the field of study*:

Object reference is a sequential process of selection, representation, and acknowledgement [1]. Although there has been extensive research conducted on different approaches for selection, representation, and acknowledgment [2-5], there appears to be relatively little research focused on understanding characteristics of object hand referencing in AR and how these characteristics affect design guideline for AR specific UI.

[1] J. Chastine, Y. Zhu and J. Preston, "A Framework for Inter-referential Awareness in Collaborative Environments", 2006 International Conference on Collaborative Computing: Networking, Applications and Worksharing, 2006. Available: 10.1109/colcom.2006.361859

[2] R. Kopper, F. Bacim and D. Bowman, "Rapid and accurate 3D selection by progressive refinement", 2011 IEEE Symposium on 3D User Interfaces (3DUI), 2011. Available: 10.1109/3dui.2011.5759219

[3] R. Bolt, "“Put-that-there”", Proceedings of the 7th annual conference on Computer graphics and interactive techniques - SIGGRAPH '80, 1980. Available: 10.1145/800250.807503

[4] T. Grossman and R. Balakrishnan, "The design and evaluation of selection techniques for 3D volumetric displays", Proceedings of the 19th annual ACM symposium on User interface software and technology - UIST '06, 2006. Available: 10.1145/1166253.1166257

[5] I. Poupyrev, M. Billinghurst, S. Weghorst and T. Ichikawa, "The go-go interaction technique", Proceedings of the 9th annual ACM symposium on User interface software and technology - UIST '96, 1996. Available: 10.1145/237091.237102

* 1. *Describe any relevant preliminary data*:

A preliminary study is conducted to test whether different spatial relation between collaborators could influence the performance of object hand reference. 3 pairs of pilots were recruited, and we measured object referencing time and accuracy. We observed trending influence but failed to reveal any significant result.

* 1. *Based on the existing literature, provide the scientific or scholarly rationale for and significance of your research and how will it add to existing knowledge*:

With the development of AR technology, referencing virtual content for collaboration will become more and more common in daily life. Meanwhile, using a finger or a hand is a natural method for users to conduct such activity. The proposed research aims to develop and provide guidelines for efficient UI design for object hand referencing. The result should be applicable to AR users in general.

# Study Endpoints

* 1. *Describe the primary and secondary* ***study*** *endpoints. See links below for discussion of study endpoints and how they may differ from study objectives. These are most common in clinical trials but are sometimes applicable to other types of biomedical research, as well as social, behavioral, or educational research. See link below for a discussion.*

[*https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO\_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing*](https://docs.google.com/document/d/1Wocz7K7a0hCQJPPO_khh5l1SQQjhGDDGHzcOPRHR5Tw/edit?usp=sharing)

We will finish the study until we have enough number of participants to validate the system. As of now we plan to recruit up to 60 people. Not applicable.

* 1. *Describe any primary or secondary* ***safety*** *endpoints. These should be included for all studies that are greater than minimal risk. (Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*:

We will finish the study if we find any safety issue in the environment in which we conduct the study. In addition, if we find any safety vulnerable points in the task, which is referencing a virtual or physical object, we will end the study.

# Study Design and Statistical Analysis Plan

* 1. *Describe the basic study design/approach (e.g., qualitative study using five focus groups of first year students to describe assimilation into the university community; randomized controlled trial of a behavioral change intervention to increase dietary intake of whole grains; pre- post-test evaluation of new pedagogical techniques to improve adult literacy)*:

The participants will perform a collaborative interaction task comparing hand referencing of objects in the real world and Augmented Reality (AR) setup. The task primarily includes two users at the same time; one person referencing an object among many and the other person who recognize which object the pointer is pointing at. We will measure participants performance in terms of accuracy and task completion time, as well as qualitative feedback such as confidence level and user experience. We will also take video at participants' hand gestures. Audio recording of the entire experiment session will also be included.

* 1. *Describe corresponding data analysis plan/approach (e.g., content analysis of focus group transcripts; descriptive analysis followed by linear regression modeling; nonparametric analysis of pre- and post-test measures)*:

The data will be analyzed with various statistical tests such as linear regression to determine the effect of predict factors on task performance.

# Setting

* 1. *Describe the sites or locations where your research team will conduct the research. Consider each of the items listed below:*
     + *Identify where your research team will identify and recruit potential subjects.*
     + *Identify where the team will perform the research procedures.*
     + *Describe the composition and involvement of any community advisory board(s).*
     + *For research conducted in other locations, describe:*
       - *Site-specific regulations or customs affecting the research at those locations.*
       - *Local scientific and ethical review structure at those locations.*

*Examples include work in other cultures or ethnic groups (within or outside of the U.S.) and work with churches. The HRPP will provide additional guidance for international research.*

The study will be conducted at the Usability Lab 133 (D, E, F) (102 McBryde Hall).

# Study Intervention(s)/Investigational Agent(s)

*7.1 Describe the study interventions (including behavioral interventions) and/or investigational agents (e.g., drugs or devices) to be used in this study. Consider each of the items listed below:*

* + - *Drug/Device Handling: If the research involves drugs or devices, describe your plans to store, handle, and administer the drugs or devices so that they will be used only on subjects, and only by authorized investigators.*
    - *Describe whether any of the following will be used: microwaves, X-rays, DEXA scans, general anesthesia, or sedation*
    - *If control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference the SOP in this section.*

N/A

* 1. *List the name of all drugs (including any vitamins, supplements, herbs, or nicotine) to be used in the study. Indicate whether they have FDA approval, and list any limitations for their use*:

N/A

* 1. *List all devices, how they will be used, their purpose in the study, and if they will be used in a manner consistent with their approved uses. If they will be used in ways that are not yet FDA approved, indicate whether they need an IDE or a determination that they are exempt from the IDE Determination. If a determination of significant risk or non-significant risk is needed for any of the devices, include the researcher’s recommendation for each of those devices*:

N/A

* 1. *If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:*
     + *Identify the holder of the IND/IDE/abbreviated IDE.*
     + *Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:*

|  |  |  |  |
| --- | --- | --- | --- |
|  | ***Applicable to:*** | | |
| ***FDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** |
| ***21 CFR 11*** | ***X*** | ***X*** |  |
| ***21 CFR 54*** | ***X*** | ***X*** |  |
| ***21 CFR 210*** | ***X*** |  |  |
| ***21 CFR 211*** | ***X*** |  |  |
| ***21 CFR 312*** | ***X*** |  |  |
| ***21 CFR 812*** |  | ***X*** | ***X*** |
| ***21 CFR 820*** |  | ***X*** |  |

N/A

# Procedures Involved

* 1. *Describe and explain the study design*:

The study is aimed to identify the possible characteristics in AR collaborative object referencing using bare hand. We will design and set up a collaborative task that requires two users to complete in both AR using virtual objects and in real world using physical probs. One user will be instructed to reference or point to one specific object using different 3D interaction approaches and the other user will be asked to identify the referenced target. We will design trials testing different hypothesized factors and the collaborators will be asked to repeat trials until finish. We record quantitative task performance data and conduct brief interview to gather subjective feedback.

* 1. *Provide a description of:*
     + *All research procedures being performed*
     + *If the study has more than one procedure, session, and/or subject population, describe each procedure, session, and/or study population separately. For complex studies, you are encouraged to include a figure or chart.*

The study will take place in the Usability Lab 133 (D, E, F) (102 McBryde Hall) and will take approximately 60 minutes for each participant.

When participants arrive, they will be greeted and asked to read and sign the informed consent form after their questions (if any) are answered. Then they will be asked to clarify they have normal vision. Next, they will be provided with written or verbal instructions for the experiment, and familiarized with the lab and the equipment they will be using. Participants will wear an augmented reality (AR) headset such as the Microsoft Hololens. Using the devices, participants will then complete a series of interaction tasks in AR and in real world, using one or more 3D interaction techniques. Tasks will involve physical movements including looking around the environment, pointing to virtual or physical objects, interacting with other UIs that ask questions regarding the objects (e.g. Which object is pointed at?) and manipulating virtual objects. After each block of tasks, participants will be interviewed by the investigator to gather qualitative feedback. Breaks will be given after each usability interview. After all tasks are completed, participants will be interviewed about their experience.

* 1. *Describe:*
     + *Procedures or safeguards intended to reduce the probability and magnitude of risks. (For example: Reducing the risk of injury in a virtual reality study either by having the subjects sit during the study or by providing an obstacle-free space for walking.)*
     + *Be sure to describe all drugs and devices used in the research, when they will be administered or used, and their purpose.*
     + *Methods used to collect data about subjects. Please upload all data collection forms to Protocol Management. Some common examples are:*
     + *Screening questionnaires*
     + *Survey(s), including online surveys*
     + *Demographic questionnaire(s)*
     + *Interview guide(s), e.g., questions or pool of questions for semi-structured interviews*
     + *Focus group guide(s)*
     + *Other documents used to collect data*

The study will take place in an obstacle-free space for minimal movement. We encourage the participants to take a rest between trials or at any point needed to avoid possible motion sickness.

Quantitative performance data will be automatically captured by the computer and AR device such as time and trial accuracy. Qualitative feedback will be recorded by the experimenter in digital documents. We will only video record users' hand gestures. The entire experiment session will be audio recorded as well.

* 1. *What data will you collect during the study and how you will obtain them? Please include descriptions of electronic data collection, database matching, and app-based data collection*:

The AR program automatically logs data of interest such as timestamps, target object ID, and user selection. The data will be stored in \*.csv files and exported in a password-protected desktop computer in the Sandbox for further data analysis.

The qualitative data will be stored in the experimenter's password protected computer and then transferred to the desktop computer in the Sandbox.

We will video record users hand gestures during the experiment. We will ensure only users' hands will appear in the video. We will also record the audio during the experiment session for further qualitative analysis. Both video and audio data will be stored in a password-protected desktop computer in the Sandbox.

* 1. *Who will transcribe or code audio and/or video recordings?*:

N/A

* 1. *Include a description of any deception to be used in the study. Include justification for the use of deception (why the deception is necessary), describe the debriefing process, and describe how the study meets all the following criteria for alteration of consent (deception is considered an alteration of informed consent):*
* *The research involves no more than minimal risk to the subjects*
* *The alteration will not adversely affect the rights and welfare of the subjects*
* *The research could not practicably be carried out without the alteration/deception*
* *(Optional but encouraged in most cases) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception)*

N/A

* 1. *If the study involves long-term follow-up (once all research related procedures are complete), describe what data will be collected during the follow up period and when it will occur*:

N/A

# Data and Specimen Long Term Storage and Use

* 1. *If you will store data or specimens for future use, describe where you will store the data or specimens, how long they will be stored, and how and by whom the data or specimens will be accessed*:

The experiment data will be stored in a password protected desktop computer in the Sandbox studio and will be stored for a year for possible analysis. Only the protocol investigators will have access to the data.

The consent form will be stored in EchoLab(in CRC) for 3 years after the studied has been closed. After 3 years, all consent forms will be deleted permanently.

* 1. *For specimens, list the data to be stored or associated with each specimen*:

N/A

* 1. *Describe the procedures to release data or specimens outside of the research team, including the process to request a release, approvals required for release, who can obtain data or specimens, and what data will be provided with specimens*:

N/A

* 1. *Describe the identifiers to be included with stored data or specimens, as well as any key or code that could be used to make them identifiable. Describe where the code will be stored, who will have access to it, and when it will be destroyed*:

Names will only be collected on consent forms and is not part of the stored data. Participants will only be identified by a study code on all data documents. No key linking study codes to names will be kept.

* 1. *Please select the identifiers you will obtain (whether directly from participants or from another source), including but not limited to:*

|  |  |
| --- | --- |
|  | *Name* |
|  | *Geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and equivalent geocodes (note, the initial three digits of a zip code are not considered identifiable)* |
|  | *Elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and single year of age over 89 and all elements of dates (including year) indicative of such age (note, such ages and elements may be aggregated into a single category of age 90+)* |
|  | *Phone numbers* |
|  | *Fax numbers* |
|  | *Electronic mail addresses (e-mail)* |
|  | *Social Security numbers* |
|  | *Medical record numbers* |
|  | *Health plan beneficiary numbers* |
|  | *Account numbers* |
|  | *Certificate/license numbers* |
|  | *Vehicle identifiers and serial numbers, including license plate numbers* |
|  | *Device identifiers and serial numbers* |
|  | *Web Universal Resource Locators (URLs)* |
|  | *Internet protocol (IP) address numbers* |
|  | *Biometric identifiers, including finger and voice prints (audio recording)* |
|  | *Full face photographic images and any comparable images (including video recording)* |
|  | *Student record number or identification number* |
|  | *User name for online or computer accounts* |
|  | *Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)****:*** Click here to explain. |

# Sharing of Results with Subjects

* 1. *Describe whether you will share results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) with subjects or others (e.g., the subject’s primary care physician). If so, describe how you will share the results and include this information as part of the consent document. Upload materials you will use to explain the results to subjects*:

No

# Study Timelines

* 1. *Describe:*
     + *The duration of an individual subject’s participation in the study (for example, 1 hour, 2-4 weeks, 3-5 years).*
     + *The amount of time expected to enroll all study subjects (weeks, months, years, etc.)*
     + *The amount of time expected for the investigators to complete this study including primary data analyses.*

The study takes approximately 60 minutes. We plan to recruit for four weeks. The analysis of the study result should take another four weeks.

# Inclusion and Exclusion Criteria

* 1. *Describe how you will screen individuals for eligibility. When will screening occur and what procedures will you use? Upload any screening scripts or surveys to Protocol Management*:

We will need participants who are 18 or older to obtain perfect (20/20) or corrected to perfect (glasses or contact lenses) vision. We will ask the participant for their age and vision upon signing up.

* 1. *Describe the eligibility criteria that define who will be included and who will be excluded from enrollment for each procedure of your study. Include any geographic criteria (e.g., Virginia Tech undergraduate students, a national sample of adults with engineering degrees, minors aged 8-12 in the New River Valley, university faculty in Virginia and Paris, France)*:

Perfect (20/20) or corrected to perfect (glasses or contact lenses) vision.

18 or older.

* 1. *Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate them in the description of your subject population.)*
     + *Minors, as defined by state law where the study is performed (infants, children, teenagers)*
     + *Pregnant women (can be included in minimal risk studies by mentioning in section 13.1)*
     + *Prisoners (including all incarcerated individuals)*
     + *Adults not capable to consent on their own behalf*

N/A

# Vulnerable Populations

* 1. *If the research involves individuals who are vulnerable to coercion or undue influence, please describe additional safeguards you will include to protect their rights and welfare. Consider the applicable items listed below:*
     + *If the research involves Virginia Tech students, indicate whether these are students of any of the investigators. If so, describe whether the activities will take place during class time as part of the curriculum and the steps you will take to reduce the possibility that students feel obliged to participate in order to improve their course grade. The HRPP can provide further guidance as needed. Describe whether you will request access to student records (e.g., SAT, GPA, GRE scores).*
     + *If the research involves employees of Virginia Tech or the research sponsor, describe steps you will take to ensure that the employees are freely participating and describe how their data will be protected from inspection by their supervisors.*
     + *If the research involves Virginia Tech NCAA athletes, you must obtain approval from the athletic department.*
     + *For research involving Montgomery County Public Schools, you must obtain county approval (after obtaining contingent Virginia Tech approval). Other locales have different requirements; please check on these and describe here. Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should be uploaded as a supporting document.*
     + *If the research involves pregnant women, review “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information in this protocol.*
     + *If the research involves prisoners, review “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information in this protocol.*
     + *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (minors), review the “CHECKLIST: Minors (HRP-416)” to ensure that you have provided sufficient information in this protocol.*
     + *If the research involves cognitively impaired adults, review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information in this protocol.*

N/A

# Number of Subjects

* 1. *Indicate the total number of subjects to be enrolled and how this number was determined (e.g., sample size calculation [show], number of available subjects in a finite pool, number of tests funding award would allow)*:

We plan to recruit 60 participants

* 1. *If this is a multi-site study, indicate the number of subjects to be enrolled at this site and the total to be enrolled from all sites*:

N/A

* 1. *If applicable, indicate the number of potential subjects you expect to screen for enrollment, and the number of subjects you will need to complete the research procedures*:

At most 60 participants to screen and around 30 participants to finish the study.

* 1. *If the study has more than one procedure, indicate the total number of subjects to undergo each procedure separately*:

N/A

# Recruitment Methods

* 1. *Describe when, where, and how you will recruit potential subjects*:

Participants will be recruited via email advertisement.

No reminder email will be sent to participants.

* 1. *Describe the source of subjects (for example, clinic patients with specific conditions, students in the library, community members at a gathering, or members of a local gym)*:

Participants will be recruited from the university and local community.

* 1. *Describe the methods that you will use to identify potential subjects*:

N/A

* 1. *Describe materials that you will be use to recruit subjects. Attach copies of these documents with this protocol in Protocol Management and be sure to include the IRB protocol number on each document.*
* *For flyers, attach the final copy of printed flyers.*
* *For Virginia Tech News, Facebook postings and ads, newspaper ads, websites, MTurk/SONA/online survey systems, etc., attach the final wording and graphics to be used.*
* *For email recruitments, please include the subject line.*
* *For advertisements meant for audio broadcast, please submit the wording of the advertisement prior to taping (to avoid having to re-record with approved language) and submit the final recorded version for IRB review before use.*

*Describe any compensation to subjects. Separate compensation into appropriate categories, such as: reimbursement for expenses, time and effort, and additional incentives for study participation. For each category, specify the amount (including any pro-rated amount), schedule, and method of payment.*

The 3D Interaction (3DI) group is inviting you to participate in a research study with augmented reality (AR) technologies. Our team is investigating the best ways to interact with AR and this study compares various methods of interaction with virtual content to complete collaborative tasks. The study will make use of state-of-the-art AR technologies such as Microsoft Hololens.

Participants in the study will come to the Usability Lab 133 (D, E, F) (102 McBryde Hall). Participants will be asked to complete interaction tasks such as object selection, manipulation in AR. Participants will be asked for their comments about these innovative interaction techniques. We will video record users' hands during the study and the entire session will be audio recorded. The entire experimental session will take about 60 minutes.

We are seeking participants that are:

• 18 years oand older,

• Have normal vision (glasses and contact lenses are fine)

• Can do the user study which involves AR device, fill out a survey, and answer post-study interview in English.

After the user study, each participant will be compensated with $12.

Participation will be on first come first serve basis. For more information, please contact Donghan Hu at [hudh0827@vt.edu](mailto:hudh0827@vt.edu), Boyuan Wang at [boyuan@vt.edu](mailto:boyuan@vt.edu) ,or Yuan Li at [yli92@vt.edu](mailto:yli92@vt.edu). The project is supervised by Dr. Doug A. Bowman and Dr. Sang Wong Lee in Computer Science.

This experiment has been approved, as required, by the Virginia Tech Institutional Review Board.

Each participant will be compensated with electronic gift cards ($12).

# Withdrawal of Subjects

* 1. *Describe circumstances under which you anticipate subjects could be withdrawn from the research without their consent*:

Whenever the participants wish to withdraw from the experiment.

* 1. *If applicable, describe any procedures for orderly termination (e.g., discontinuation of a study drug or debriefing after a behavioral intervention)*:

N/A

* 1. *Describe procedures that you will follow when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection (e.g., participant declines to continue with regular blood draws, but continues with periodic behavioral questionnaires)*:

The participant's currently collected data will be destroyed.

# Risks to Subjects

* 1. *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Include for the IRB’s consideration a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, privacy, and economic risks. Do not indicate “No risk” or “N/A.” Instead, for studies with very low risk (e.g., anonymous online questionnaire on a mundane topic) indicate “The investigators are not aware of any risks from participation in this study.” or “No more than risks than are found in everyday life.” The example consent form presents a tabular method for risk information, which you can also use here. Common risk types include:*
* *Physical (e.g., potential for pain, discomfort, infection)*
* *Psychological (e.g., potential for stress, discomfort, and/or embarrassment)*
* *Social (e.g., potential for discrimination or stigmatization and disruption of personal and family relationships)*
* *Legal (e.g., potential for disclosure of illegal activity, negligence)*
* *Privacy (e.g., potential for personal information being accessed, used, or disclosed without the subjects’ knowledge or consent, breach of confidentiality/security)*
* *Economic (e.g., potential for individuals to lose access to economic services, employment, insurability)*

Using AR technology can produce symptoms of sickness or discomfort in some users. These symptoms are usually mild, and may include dizziness, nausea, eye strain, headache, or disorientation. During tasks involving physical movement, there is also some risk that participants will collide with obstacles in the physical environment, or contact the physical cables connecting the display to the computer.

* 1. *Indicate the measures you will use to minimize risks and monitor subjects for safety. (e.g., asking a subject at regular intervals to rate how they are feeling from 1 to 10, or to slowly crouch in order to check their balance.)*

Participants will be informed about the potential risks and will be given the option to take a break or quit the experiment at any time. To mitigate the risk of sickness and discomfort, we will adjust the display properly for each user, keep task sessions short, provide frequent breaks, and ask the participant after each set of tasks how they are feeling. To mitigate the risk of physical obstacles, we will clear the area of obstacles, show the participant where the boundaries of the space are, and warn the participant if they are nearing an obstacle.

* 1. *If applicable, indicate which procedures might have risks to the subjects that are currently unforeseeable. This will be rare, and usually applicable when testing a new drug or device or a new use of an existing drug or device*:

N/A

* 1. *If applicable, indicate which procedures might have risks to an embryo or fetus should the subject be or become pregnant*:

N/A

* 1. *If applicable, describe risks to others who are not subjects (e.g., collection of sensitive health data that might affect sexual partners if disclosed, mandatory reporting of abuse, DNA testing that might affect family members or relationships)*:

N/A

# Potential Benefits to Subjects

* 1. *Describe the potential benefits that individual subjects might experience from participating in the research. Include the probability, magnitude, and duration of the potential benefits, as this will be useful to the IRB’s risk:benefit analysis. Do not include benefits to society or others. Do not list monetary or non-monetary compensation for participation, as this is not a benefit These should be included in section 2 or 3 of this document*:

The study will improve our understanding of 3D interaction design for AR, so that effective user interfaces can be designed for real-world AR applications. Study participants will benefit from exposure to state-of-the-art AR technologies and techniques.

* 1. *If applicable, specify that there are no anticipated direct benefits for participants*:

N/A

# Data Management and Confidentiality

* 1. *Describe procedures that you will use for quality control to ensure validity of collected data*:

The investigator will closely follow pre-defined procedure to ensure the experiment going smoothly.

* 1. *Describe any existing data or biospecimens you will obtain as part of this study. Include:* 
     + *Variables or samples to be obtained*
     + *Source of the data or specimens*
     + *Your authorization to access or receive the data or biospecimens*
     + *Whether the data or biospecimens are publicly available*
     + *Whether the data or specimens you receive will contain identifiers*

N/A

* 1. *Describe the steps that you will take to handle and secure study data during data collection, storage, use, and transmission. Include information about training of study staff, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data, etc.*:

All data will be stored digitally on a password-protected desktop computer in the Sandbox studio.

* 1. *For multi-site studies, describe how data or specimens will be handled and secured for each site (e.g., central or disseminated data storage, data coordinating center)*:

N/A

* 1. *Describe the plan for data disposition following the conclusion of the study (e.g., long term maintenance of data, data destruction methods).* 
     + *What information will be included in the long term storage of data or specimens?*
     + *How long will the data or specimens be stored?*
     + *Where and how data or specimens will be stored?*
     + *Who will have access to the data or specimens during long term storage?*
     + *Who is responsible for receipt or transmission of the data or specimens?*
     + *How will data or specimens be shared or transported?*
     + *When and how will personal identifiers be destroyed?*

The consent forms will be stored in EchoLab(in CRC) for 3 years after the user study has been closed. After 3 years, all the consent forms will be deleted permanently.

All collected data (time, accuracy, qualitative feedback) will be stored for careful investigation for a year. All data will be stored digitally on a password protected desktop computer in the Sandbox studio. Only the investigators will have access to the stored data. The data will not be shared. Personal identifier is not stored.

# Provisions to Protect the Privacy Interests of Subjects

* 1. *Describe the steps that you will take to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information (e.g., collecting the minimal amount of private information required to complete the study, protecting the data once it is obtained)*:

We will only ask for a minimal amount of private information from the participants and will store such data in a password protected computer in the Sandbox studio.

* 1. *Describe steps that you will take to make subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures (e.g., use of a same gender investigator to place sensors on the torso, a private changing area if clothing must be changed, sensitivity when discussing pregnancy testing with subjects, making it clear on surveys that participants can discontinue at any time, not asking questions about private or sensitive issues unless necessary for the research)*:

The participants will be frequently asked about their feeling and tiredness and are invited to take a break at any point of the study.

* 1. *Describe how you plan to access existing sources of information about the subjects (e.g., medical records, grades) and how you will protect participant privacy through the data security plan*:

N/A

* 1. *Describe any required reporting that might occur as a result of your research questions, study populations, and data collection methods. Examples for Virginia and Virginia Tech include:*
  + ***Any*** *suspicions (e.g., circumstantial, disclosed) of child abuse (physical, emotional, sexual) and neglect*
  + *Sexual discrimination and/or sexual violence that involves a student*
  + *Disclosure or signs of intention to harm oneself (i.e., suicidal ideation and/or plan)*
  + *Disclosure or signs of desire to harm others (i.e., homicidal ideation and/or plan)*
  + *Suspected abuse, neglect or exploitation of vulnerable adults (e.g., individuals with a disability, elderly persons)*

N/A

# Provisions to Monitor the Data to Ensure the Safety of Subjects

*Safety monitoring is required* *when research involves greater than minimal risk and is sometimes appropriate for other studies.*

* 1. *Describe:*
     + *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe (e.g., periodic reporting to the IRB, establishing a data monitoring committee, reporting data monitoring committee findings to the IRB and the sponsor).*
     + *What data you will review, including safety data, unexpected events, and data that show the ability to produce the intended results.*
     + *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects).*
     + *The frequency of data collection, including when safety data collection starts.*
     + *Who will review the safety data and with what frequency.*
     + *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
     + *Any conditions that will trigger an immediate suspension of the research (e.g., a serious adverse event).*

N/A

# Compensation for Research Related Injury

* 1. *If the research involves more than minimal risk to subjects, describe the available compensation in the event of research-related injury, if any*:

N/A

* 1. *Provide a copy of contract language, if any, relevant to compensation for research-related injury. At Virginia Tech, this is most common for sponsored research*:

N/A

# Economic Burden to Subjects

* 1. *Describe any costs that subjects might be responsible for because of participation in the research, including any uncompensated costs for items such as transportation, missed work, and childcare*:

N/A

# Consent Process

* 1. *Indicate the process by which you will obtain consent for study participation. Please upload all consent, parental permission, and assent forms, documents, and scripts referenced in this section to Protocol Management.*

*Describe the following:*

* + - *Where the consent process will take place (e.g., clinic waiting area, classroom, online)*
    - *The time interval between sharing the consent information with the prospective subject and obtaining consent. For lab, interview, and focus group studies, the Virginia Tech IRB prefers that subjects have at least 24 hours to review the consent form and study information before the appointment where consent will be obtained. For simple online survey studies, you can typically present the consent information immediately before subjects begin participation.*
    - *If applicable, processes to ensure ongoing consent or assent (e.g., for multiple sessions; for research in which a minor will turn 18 during the study; for longitudinal research with minors who will later be asked to provide or affirm their assent).*
    - *Please review “SOP: Informed Consent Process for Research (HRP-090)” for recommended procedure. Describe your process, being sure to include:*
      * *The name and role of all study personnel who will be trained and certified by the PI to conduct the consent process*
      * *The time that will be devoted to the consent discussion*
      * *Steps that you will take to minimize the possibility of coercion or undue influence*
      * *Steps that you will take to gauge or ensure the subjects’ understanding*

A consent form will be presented to the participants upon arriving at the Sandbox studio. Participants will be asked to read and sign the consent form prior to any experiment procedure. Yuan Li, Donghan Hu and Boyuan Wang will be trained and certified by the PI to conduct the consent process.

***Non-English Speaking Subjects***

* + - *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
    - *If non-English speakers will be recruited, describe the process you will use to ensure that the oral and/or written consent information provided will be in a language that they understand.*
    - *If you translate consent forms and study materials, please provide a certified translation of the form as well as the certification document.*
    - *Indicate the spoken language that study personnel obtaining consent will use. Describe how you will assess fluency of personnel obtaining consent to ensure that the translation is accurate.*

N/A

***Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)***

* + - *Review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure you have provided sufficient information for the IRB to make these determinations (i.e., that it meets the criteria for a waiver or alteration of the consent process).*

N/A

***Subjects who are not yet adults (minors: infants, children, teenagers)***

* + - *Describe the criteria that you will use to determine legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g., in Virginia, individuals under the age of 18 years).*
      * *For research conducted in Virginia, review “SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)” to determine which individuals in the state meet the definition of “minor.”*
      * *For research conducted outside of the state, please describe the legal requirements for the definition of “minor.”*
    - *Describe the process for obtaining parental permission.* 
      * *Permission from one parent is acceptable for studies that involve no greater than minimal risk OR involve greater than minimal risk but present the prospect of direct benefit to the minor subject.*
      * *Permission from both parents is required in all other cases (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the minor).*
    - *Describe whether you will obtain permission from individuals other than parents or Legally Authorized Representatives, and if so, who will be allowed to provide permission. Describe the process you will use to determine these individuals’ authority to consent to the minor’s general medical care.*
    - *Indicate whether you will obtain assent from all, some, or none of the minors. If you will obtain assent from some minors, indicate which minors will be required to assent. Consider chronological age and intellectual capacity when determining who will be required to provide assent (e.g., infants are unable to assent. However, teenagers are likely able to read and sign an assent form).*
    - *When assent of minors is obtained, describe whether and how you will document it. Will minors sign an assent form or give verbal assent?*
    - *Attach parental permission and minor assent forms or scripts in Protocol Management.*

N/A

***Adults Unable to Consent***

* + - *Describe the process you will use to determine whether an individual adult is capable of consent.*
    - *List the individuals from whom you will obtain permission in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and non-minor child).*
      * *For research conducted in the Virginia, review “SOP: Legally Authorized Representatives, Minors, and Guardians (HRP-013)” to determine which individuals in the state meet the definition of “legally authorized representative.”*
      * *For research conducted outside of Virginia, please describe the legal requirements for obtaining permission from a legally authorized representative in the state where the research will occur.*
    - *Describe the process for assent of the subjects.*
      * *Indicate whether you will require assent from all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.*
      * *If you will not obtain assent from some or all subjects, please provide justification for not obtaining assent.*
      * *Describe whether and how you will document assent.*

N/A

# Process to Document Consent in Writing

* 1. *Consult “SOP: Written Documentation of Consent (HRP-091)” for recommended procedures, and describe whether and how consent of the subject will be documented in writing*:

Upon arrival at Sandbox studio, the participant will be asked to read and sign a consent form prior to any experiment procedure.

* 1. *If the research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, you can request that the IRB waive the requirement to obtain written documentation of consent (e.g., consent to participate is indicated by pressing a button for an online questionnaire – after the consent information is presented and before the questionnaire begins)*:

N/A

* 1. *If you will document consent in writing, attach a consent document with places for signatures. If you will obtain consent, but not document consent in writing, please attach the consent script or text. Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information. You should use “TEMPLATE CONSENT DOCUMENT (HRP-502)”to create the consent document or script*:

N/A

# Resources Available

* 1. *Describe the resources available to conduct the research. For example, as appropriate:*
     + *Describe the PI’s availability to supervise the research.*
     + *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
     + *Describe the time that you will devote to conducting and completing the research.*
     + *Describe your facilities.*
     + *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated or unanticipated consequence of participation in the research.*
     + *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions (e.g., training plans, detailed study notebooks).*

In prior experience, we can recruit seven participants on weekly basis, therefore it is probable to successfully recruit 30 participants in four weeks. The experiment will take place in the summer before August. Sandbox studio is a lab for virtual reality and AR studies with many state-of-the-art devices.

# Multi-Site Research

*Contact the HRPP for multi-site research (involving multiple institutions) and the details required for this section will be provided. Otherwise, indicate N/A.*

N/A