Protocol Document

Official Title: THREE-DIMENSIONAL ADVANCED TEACHING MODALITIES FOR IMPROVING LEARNERS' UNDERSTANDING OF CONGENITAL HEART DISEASE

Document Date: 10/10/2024

NCT: NCT07295730

Use this exemption request protocol template as a guide for protocols anticipated to meet the criteria for exemption.

Instructions

- *• Use this template to prepare your IRB Protocol. Carefully complete the protocol.*
- *• DO NOT open or edit in google docs.*
- *• DO NOT upload PDFs of protocol or consent forms. Use PDFs sparingly.*
- *If the IRB determines your study does not meet the criteria, additional protocol elements will be required.*
- *Depending on the nature of what you are doing, some sections may not be applicable to your research.* ***If so, please mark "n/a."***

Justification for IRB Exemption
(Please follow the link in blue for the category you feel applies for the full definition; if you are not sure something fits, please contact IRB at IRB-CWRU@case.edu)
45 CFR 46.104(d) defines those human research activities that are exempt from IRB review.
Note:

- the exemptions below do not apply to research involving prisoners, except for research that only incidentally includes prisoners
- the exemptions 1-5 do not apply if the research involves an FDA-regulated product or you intend for the results of your research to be later submitted to, or held for inspection by, the FDA

Please check the box(es) to indicate which of the following categories most clearly represents your research:

☒ (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Do not use this if the educational method is only used as a part of the study.

***This category does not apply if a study is merely taking place in an educational setting without meeting the other criteria.*

☒ (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.

******Children cannot be included*** *in research under this exemption, except for research only involving educational tests, or observations of public behavior when the investigator(s) will not participate in the activities being observed.*

☒ (3) Research involving benign behavioral interventions (BBI) through verbal, written responses (including data entry or audiovisual recording) from adult subjects who prospectively agree. Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

*** **Children cannot be included** in this category. **Do not click this if you are only doing a survey, focus group or interview with no behavioral intervention.*

☐ (4) Secondary research for which consent is not required: use of identifiable information or identifiable biospecimens that have been or will be collected for some other primary or initial activity.

***Identifiable biospecimens may only be included if they are publicly available or if the research is conducted by or on behalf of a Federal department or agency.*

☐ (5) Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads and designed to study public benefit or service programs.

☐ (6) Taste and food quality evaluation and consumer acceptance studies.

Important: The categories (numbers) above are linked to the regulations containing important details and specific qualifiers.

PROTOCOL TITLE:

Include the full protocol title.

THREE-DIMENSIONAL ADVANCED TEACHING MODALITIES FOR IMPROVING LEARNERS' UNDERSTANDING OF CONGENITAL HEART DISEASE.

PRINCIPAL INVESTIGATOR:

Name: Arpit Agarwal, MD, Division of Pediatric Cardiology at Rainbow Babies and Children's Hospital

Is this a student led study?

☐ Yes ☒ No

If yes, is the student: ☐ Undergrad ☐ Graduate Student ☐Other *Click here to enter text.*

If yes, is the project:

☐ Course Requirement ☐ Capstone ☐ Master's thesis ☐ PhD dissertation ☐Other *Click here to enter text.*

Is this work part of a larger collaborative research project where more than one institution is participating in the research? (*In collaborative projects, data/specimens/results are often shared between researchers at the participating institutions, and they will publish together.)*

☒ No ☐ Yes

If yes, please explain.

Click here to enter text.

1.0 Objectives

Describe the purpose, specific aims, or objectives.

The main purpose of this study is to evaluate the effectiveness of three-dimensional (3D) teaching modalities (3D models/ Augmented reality) on complex congenital heart disease.

Specific Aims: 1. To evaluate the effectiveness of three-dimensional (3D) teaching modalities (3D models/ Augmented reality) on medical student understanding of complex congenital heart disease. 2. Compare the use of Mixed reality / Augmented reality, 3D models, and traditional method of teaching (lecture and powerpoint)

2.0 Inclusion and Exclusion Criteria

Using the tables below, describe the inclusion and exclusion criteria that will define who will be included and excluded in your final study sample.

	Inclusion
1.	First- or second-year medical student at Case Western Reserve School of Medicine
2.	
3.	
4.	

	Exclusion
1.	Previous cardiology experience through research or clinical experience
2.	
3.	
4.	

3.0 Local Recruitment Methods

3.1 How many participants do you plan to recruit? (This is an upper limit) 360

3.2 Which of the following methods will be used to recruit research participants? – *Select all that apply.*

- ☒ Email
- ☐ Letter
- ☐ Phone call
  - *Note: Phone calls can only be made after the study has been introduced in person, by letter, or email. Cold calling is not generally permissible.*
- ☐ Advertisement (e.g., poster, flyer, etc.)
  - ☐ I attest that advertisements will only be placed **with permission**
- ☐ Social media:
  - Indicate the platform(s): *Click here to enter text.*

☐ I attest that recruitment information will only be posted **with permission**

☐ Snowball sampling

☐ Other: *Click here to enter text.*

3.3 Describe when, how and by whom potential research participants will be recruited. If recruiting in person, please describe where you will be recruiting. Include how you will protect the confidentiality of identifiable information used for recruitment (such as email addresses). Individuals involved in recruitment should be identified by role and not by name (e.g. study coordinator, co-investigator, research assistant).
A mass email from a member of the research team will be sent to their CWRU email addresses at the beginning of the 2024-25 academic year. Emails will not be shared outside of the researchers in this study and will only be utilized to document agreement to participate in the study and for dissemination of surveys.

Attach all applicable recruitment materials in the "Recruitment Materials" section of the Local Site Documents page.

4.0 Research Participants

4.1 Indicate if you will specifically recruit any of the following special populations:

☐ Adults unable to consent
☐ Minors (up to age 18) (If selected, this study may not qualify for exemption.)
☐ Pregnant Women
☐ Neonates
☐ Employees
☐ Prisoners (If selected, this study does not qualify for exemption.)
☐ Illiterate Individuals
☐ Non-English Speaking
☒ Students
☐ Data on a subjects' specific tribal nations
☐ None

4.2 If the research involves students or employees, describe the how you will recruit so that:
a) Employers or educators do not know if someone participated (until after grades have been assigned in the case of educators).
b) Employers or educators do not directly recruit their own students or employees, and anything else to prevent feelings of coercion to those subordinate to their employer or educator.

No CWRU faculty will have access to identifiable data of students nor will they be present for teaching sessions using the modalities. Therefore, no faculty will be aware of a student's participation in the study. Data analysis will not include identifiable data.

5.0 FERPA Authorization

5.1 Does this study collect, access, use, or distribute any personally identifiable information from student records or personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education)? This includes, but is not limited to, classroom assignments and course evaluations.

☐ Yes ☒ No

5.1.1 If yes, how do you plan to get written authorization from the student (or parent if the student is a minor)?

☐ I will incorporate FERPA language[1] into the consent and obtain written and dated signature or authorized electronic signature using REDCap

☐ I will incorporate FERPA language* into a separate form and obtain written and dated signature or authorized electronic signature using REDCap

6.0 Interaction with Research Participants/Consent Process

6.1 Will there be interactions with research participants? Interactions can include electronic surveys.

☒ Yes ☐ No

6.1.1 If yes, explain who will obtain consent and the process for obtaining informed consent.

Consent will be obtained at each phase of the study from the surveys to the teaching session itself. The procedures of the study will be explained by the investigator sending the email and the investigators leading the teaching sessions. They will be informed participation in this study is optional and has no bearing on their grades.

6.2 Indicate how consent will be documented:

☒ Implied consent by completion of survey/questionnaire

☒ I will provide subjects with a written explanation of the research

☐ Verbal consent given and documented in research notes

* FERPA language: 1. Specify the educational records that may be both accessed and used in the research. 2. State the purpose of the access and use of records. 3. Identify to whom the records disclosure may be made

Please justify if you are not providing a written explanation of the research:
Click here to enter text.

☐ Informed consent document with signature

☐ Other, please explain: *Click here to enter text.*

Be sure to upload a consent script or information sheet in the "Consent Forms" section on the Local Site Documents page. The consent process must: (1) disclose that the activities are research, (2) document the procedures to be performed and the time commitment involved, (3) indicate that participation is voluntary, and (4) provide the name and contact information for the investigator.

7.0 Study Design/Procedures

Describe all study related procedures being performed, including the length of time required by participants (if applicable) and any compensation that will be provided.

A prospective randomized controlled study will be conducted with first- and second-year medical students. The study aim is to evaluate and compare three different teaching techniques for congenital heart disease. The three modalities will be PowerPoint, 3D-printed model, and advanced holographic imaging via Microsoft HoloLens. A brief teaching module will be created on complex congenital heart disease – Tetralogy of Fallot and hypoplastic left heart syndrome (HLHS) – from Moss and Adams, "Heart Disease in Infants, Children, and Adolescents." The module will contain information on anatomical and physiological variations in patients with these defects compared to those with unaffected hearts. Next, three teaching modalities will be created to deliver the module to the participants. A content expert will review the module and the presentations for consistency and accuracy. Cardiology attendings (subject experts) will create the study curriculum. No part of this curriculum will involve interaction with patients, study subjects, or PHI. Study curriculum will be developed prior to subject recruitment. The students' instructors will not take place in the implementation of the study.

Three teaching modalities will be employed: PowerPoint presentation, presentation utilizing 3D-printed models, and presentation utilizing mixed reality via HoloLens. As part of the advanced 3D imaging program at this institution, 3D models of patients' hearts are printed for pre-surgical planning purposes. The files of cardiac CT scans of patients with complex congenital heart disease will be de-identified, accessed, and utilized for the purpose of this study. A segmented model of hearts affected with Tetralogy of Fallot and HLHS will be created from the 3D cardiac CT images. The model will be converted into a 3D printer compatible file and will be sent for printing to our regular vendor (ThinkBox). A Microsoft HoloLens will also be utilized. This device is a gateway to mixed reality. A segmented model of the same three cardiac pathologies will be created from 3D cardiac CT scans and will be converted into a HoloLens compatible file. It will then be subsequently sent to OneDrive to be seen by Microsoft HoloLens.

Next, in order to enable comparison between the cohorts, a short questionnaire will be developed containing 15 multiple choice questions on anatomy and physiology of complex congenital heart

defects. Exam questions will be standardized and include first- and second-order questions addressing both the anatomy and physiology. The same questionnaire will be delivered to test the knowledge of participants prior to receiving educational intervention, immediately after, and four weeks later.

A mass email will be sent to the entire class, inviting them to participate in the study. This email will be sent by a member of our research team, a fellow medical student. Potential participants will be given information about the study and asked to read and sign an informed consent document describing the study purpose and voluntary participation. In order to protect the identity of the student participants, they will create an identifying code that will appear in the data set containing test scores. The code will consist of the last three digits of their phone number and first three letters of their mother's name. This code will be used in place of their name for each test. Members of the study team will therefore be blind to the identities of students who completed the tests. The identities of participants will also in no way be made available to instructors at the medical school. In order to ensure that all students willing to volunteer can participate, we will offer multiple sessions, one on Monday or Wednesday and another on Tuesday or Thursday. If the number of participating students is large, we will offer additional sets of sessions as needed to accommodate all students interested in participating.

The participants will be randomly assigned into three study groups/cohorts; namely A, B, and C. The participants in group A will receive a 30 minute traditional lecture with the help of PowerPoint presentation on two complex congenital heart diseases (Tetralogy of Fallot and HLHS). The participants in group B will receive a 30 minute teaching on the same two congenital heart defects using 3D printed models of the pathologies. The participants in group C will receive a 30 minute teaching session on the same pathologies using mixed reality models via HoloLens. All study participants will be asked to agree to complete pre- and post- quizzes on paper during each session. Following the conclusion of the study, all participants will be invited to a session with all modalities and given the opportunity to interact with them along with physician instructors.

8.0 Provisions to Protect the Privacy Interests of Research Participants

Indicate the measures that will be taken to protect research participants' privacy interests. Select all that apply:

- ☒ In person interactions will be conducted in a private space where conversations would not be overheard by others – this could be at a specific location determined by the research team or at a location that the participant chooses.
- ☐ For online/remote data collection, participants will be advised to choose a location that would be private.
- ☐ For focus groups, participants will be requested to keep discussions confidential.
- ☒ Researchers will only contact participants if permission has been given to do
- ☐ Other, please explain:

  Click here to enter text.

Data to be Collected

8.1 Check all that apply:

☐ Audio recordings*

☐ Video Recordings or CTs or MRIs of heads)*

☐ IP address

☒ Name and/or contact information

- ☐ Will be linked to the research data
- ☒ Will not be linked to the research data (the study procedures should describe how this will be done)

☒ Surveys/questionnaires

☐ Behavioral intervention data

☐ Interview/focus group responses

☐ Observational data

☐ Other (Please describe): *Click here to enter text.*

☐ None

*-Please note, audio or video recordings on smart phones is not allowed. Devices must be encrypted.

Be sure to upload any surveys, focus group scripts or other related materials in the "Other Attachments" section on the Local Site Documents page.

9.0 Confidentiality of Data

Collection

Online

☐ We will not collect data through an online platform

9.1 List the online platform to be used. The preferred platforms for surveys are REDCap and Qualtrics, and the preferred platform for remote interviews and focus groups are CWRU Zoom. These provide good data security and have options for collecting data without individually identifiable information. Other platforms may require review by Utech.

REDCap

9.2 If your intent is to collect the data without identifiers linked to an individual (including IP addresses), describe how you will ensure that no identifiable information will be associated with the data.

- ☐ Qualtrics: enable Anonymize Responses setting (removes IP addresses and location data)
- ☒ REDCap: use of the Public Survey Link
- ☒ REDCap: use of a Participant List without a Participant Identifier field

(Note: this does maintain a connection between the data and the individual, but it is only accessible to REDCap support personnel and not the researchers. Data collected in this manner should not be referred to as anonymous, but rather as data that is deidentified to the researchers)

☐ Other: *Click here to enter text.*

Excluding the above, are you using any cloud-based software or websites (i.e data has to go over the internet to be processed) to analyze data?
If so, please list below. E.g., transcription services, qualitative analysis services, etc. You may be asked to provide more information.

☐ Yes Please describe: *Click here to enter text.*

☒ No

Paper

☒ We will not collect data on paper

9.3 Describe how the data collected on paper will be protected until they are in the possession of the study team. For example, if you are collecting surveys in a box or envelope, how will you ensure papers cannot be taken or looked at by those not on the study team? *Click here to enter text.*

Storage

9.4 Storage location of electronic data (choose all that apply):

☒ CWRU REDCap

☐ CWRU Secure Network Drive, Which one?: *Click here to enter text.*

☐ Secure Research Environment (SRE)

☐ Box

☐ OnCore

☐ Zoom cloud

☐ Portable device

☐ I attest that any recordings (audio or video) will be done on encrypted devices. (must be encrypted, not just password protected; If I am not sure if my device is encrypted, I will consult with Utech.)

☐ Other: List storage method and provide justification: *Click here to enter text.*

9.5 To maintain the confidentiality of the data:

☒ I will use a unique study identifier to code individuals' identifiable data and will store the master list separate from the study data.

☐ I will use a unique study identifier to code individuals' data, but it will never be linked to a master list.

☐ Other- please explain: *Click here to enter text.*

9.6 ☐ Paper research data and documents will be stored in a double-locked secure environment in the following location:
Click here to enter text.

Data Sharing/Transfer

9.7 Will data be shared outside of this institution? If yes, please explain. Include what data, to whom and through what method (e.g. CWRU Box, etc.)
No

9.8 Will you be collecting data off campus? If yes, please explain how you will securely move the data back to CWRU.
No

If sharing data, please complete a request to ensure the proper contracts/agreements are in place: https://case.edu/research/faculty-staff/technology-transfer/material-transfer-data-use-agreements

Data Destruction

9.9 Provide a plan to maintain or destroy identifiers once analysis of identifiable information is complete. Once students' pre-, post-, and delayed intervention surveys are linked (for the purpose of being able to assess effect of the teaching sessions) the list containing identifiers will be destroyed.

☐ I attest that any recordings (audio or video) saved to a portable device will be deleted by formatting the device's storage memory.

10.0 Additional Information

Click here to enter text.

Principal Investigator Responsibilities

☒ I attest to the following, as applicable:

- Supervisors will not be involved in requesting participation of subjects who report to them directly at CWRU or UHHS.
- Professors will not be involved in recruitment of their own students.
- Students who receive extra credit for participation will have the option of earning extra credit through an alternative assignment.
- The consent process will disclose:
  - The activity involves research
  - A description of the procedures
  - That participation is voluntary

- The name and contact information for the researcher

- The privacy of the participants will be maintained.
- All funders/sponsors associated with this project are aware that this has been submitted to the IRB as “Exempt” research.