Expedited / Full Board Review Application
Clemson University (CU) Institutional Review Board (IRB) **(Version 9.7.2012)**
Clemson University IRB Website

Office use only	Protocol Number:
Approved ☐ Expedited ☐ Full Board	Expiration date: _____
_____ Signature of IRB Chair / Designee	_____ Date

Level of Review (Questions 13 & 14 determine if the protocol can be expedited**):** ☒ Expedited ☐ Full Board

1.	**Developmental Approval:** If you already have developmental approval for this research study (you should know if you do), please give the IRB protocol number assigned to the study. More information available here.

2.	**Research Title:**	Lie Detection in Virtual Reality
	If different, title used on consent document(s)	
	If class project, include course number and title	

3.	**Principal Investigator (PI):** The PI must be a member of the Clemson faculty or staff. You cannot be the PI if this is your thesis or dissertation. The PI must have completed IRB-approved human research protections training. Training will be verified by IRB staff before approval is granted. Training instructions available here. CITI training site available here.	
	Name: Andrew T. Duchowski	☒ Faculty ☐ Staff
	Department: School of Computing	E-mail: andrewd@cs.clemson.edu
	Campus address: 309 McAdams Hall, Clemson University	Phone: 864 656 7677
		Fax:

4.	**Co-Investigator(s):** Co-Investigators must have completed IRB-approved human research protections training. Training will be verified by IRB staff before approval is granted. Training instructions available here. CITI training site available here.		
	Name: Judsen Hembree		E-mail: jhembre@g.clemson.edu
	Department: School of Computing		Phone: 864 506-3011
	☐ Faculty ☐ Staff	☒ Graduate student ☐ Undergraduate student	☐ Other. Please specify.
	Name: Jason Strickland		E-mail: jstric8@g.clemson.edu
	Department: School of Computing		Phone: 334 462 5585
	☐ Faculty ☐ Staff	☐ Graduate student ☑ Undergraduate student	☐ Other. Please specify.

5.	**Additional Research Team Members:** All research team members must have completed IRB-approved human research protections training. Training will be verified by IRB staff before approval is granted. Training instructions available here. CITI training site available here.
	☑ List of additional research team members included. Form available here.

6. Research Team Roles: Describe the role of each member of the research team (everyone included in Items 3, 4 and 5), indicating which research activities will be carried out by each particular member. Team members may be grouped into categories.

Description: Dr.Andrew Duchowski - PI - oversees experimental design and supervision of project.
Judsen Hembree - Co-investigator - provides stimulus, experimental design setup and implementation
Kevin Lin - Co-investigator - provides stimulus, experimental design setup and implementation
Jason Strickland - Co-investigator - provides stimulus, experimental design setup and implementation
Zachary Norman - Co-investigator - provides stimulus, experimental design setup and implementation

7. Email Communications: If you would like one or two of your team members (in addition to the PI) to be copied on all email communications, please list these individuals in the box below.

Name: Judsen Hembree	E-mail: jhembre@g.clemson.edu
Name:	E-mail:

8. Study Purpose: Provide a brief description of the purpose of the study. Use lay language and avoid technical terms. IRB members not familiar with the area of research must understand the nature of the research. Upon conclusion of the study, how will you share your results (e.g., academic publication, evaluation report to funder, conference presentation)?

Description: Use the Vive pro eye to measure pupil diameter and use eye tracking data for lie detection.

9. Anticipated Dates of Research:

Anticipated start date (may not be prior to IRB approval; may be "upon IRB approval"): upon IRB approval

Anticipated completion date (Please include time needed for analysis of individually identifiable data): 11/01/22

10. Funding Source: Please check all that apply.

☐ Submitted for internal funding
☐ Internally funded
☐ Submitted for external funding
  Funding source, if applicable (Do not use initials): _____
  Proposal number (PPN) for the Office of Sponsored Programs: _____
  Name of PI on Funding Proposal: _____
☐ Externally funded
  Funding source, if applicable (Do not use initials): _____
  Proposal number (PPN) for the Office of Sponsored Programs: _____
  Name of PI on Funding Proposal: _____
☐ Intend to seek funding From whom? _____

☒ Not funded

11. Support provided by Creative Inquiry Initiative: ☐ Yes ☒ No

If yes, all Creative Inquiry students will be members of the research team, please see item # 5.

12. Other IRB Approvals:

Has this research study been presented to any other IRB? ☐ Yes ☒ No

Where? _____ When? _____

If yes, what was their decision? ☐ Approved ☐ Disapproved ☐ Pending

Please attach a copy of any submissions, approvals, or disapprovals from other IRBs.

13. Level of Risk: Does this project include any procedures that present more than minimal risk to the participants? (A project is considered to present minimal risk if the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.)
☐ Yes ☒ No

If your study presents no more than minimal risk to participants, your study may be eligible for expedited review.

14. Expedited Review Categories: The Code of Federal Regulations [45 CFR 46.110] permits research activities in the following seven categories to undergo expedited review. Please check the relevant expedited category / categories.
The Federal Office of Human Research Protections has made Decision Charts available here to help in determining whether a particular study may be reviewed using Expedited Review Procedures.

	Categories of Research that May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure
☐	1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met: a. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.) b. Research on medical devices for which 1) an investigational device exemption application is not required or 2) the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
☐	2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: a. From healthy, non-pregnant adults, who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml. in an eight week period and collection may not occur more than two times per week; OR b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount may not exceed the lesser of 50 ml. or 3 ml. per kg. in an eight-week period, and collection may not occur more than two times per week.

☐	3. Prospective collection of biological specimens for research purposes by non-invasive means. Examples: a. hair and nail clippings in a non-disfiguring manner; b. deciduous teeth at time of exfoliation or if routine patient care indicates need for extraction; c. permanent teeth if routine patient care indicates need for extraction; d. excreta and external secretions (including sweat); e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; f. placenta removed at delivery; g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; j. sputum collected after saline mist nebulization.
☒	4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; b. weighing or testing sensory acuity; c. magnetic resonance imaging; d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow and echocardiography, e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing when appropriate given the age, weight, and health of the individual.
☐	5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnoses).
☐	6. Collection of data from voice, video, digital, or image recordings made for research purposes.
☒	7. Research on individual or group characteristics, behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

15. Study Sample: (Groups specifically targeted for study)

Describe the participants you plan to recruit and the criteria used in the selection process. Indicate if there are any special inclusion or exclusion criteria.

Description: College undergraduate, graduate students and faculty at Clemson University

Age range of participants: 18 - 70 Projected number of participants: 20

☒ Employees ☒ Students ☐ Minors (under 18 in SC, may differ elsewhere) [1, 2]

☐ Pregnant women [1] ☐ Fetuses / neonates [1, 2] ☐ Educationally / economically disadvantaged [1]

☐ Minors who are wards of the state, or any other agency, institution, or entity [1, 2] ☐ Individuals who are incarcerated [1, 3]

☐ Persons incompetent to give valid consent [1]

☐ Other–specify: _____ ☐ military personnel

[1] State necessity for using this type of participant: _____

[2] Please note that research involving children (minors) requires submission of a Child Research Addendum. Further information about this addendum is given at the end of this application.

[3] Please note that research involving prisoners (incarcerated individuals) requires submission of a Prisoner Research Addendum. Further information about this addendum is given at the end of this application.

16. Study Locations:

☒ Clemson University ☐ Other University / College _____

☐ School System / Individual Schools _____ ☐ Other – specify _____

You may need to obtain permission if participants will be recruited or data will be obtained through schools, employers, or community organizations. Are you required to obtain permission to gain access to people or to access data that are not publicly available? If yes, provide a research site letter from a person authorized to give you access to the participants or to the data. Guidance regarding Research Site Letters is available here.

☒ Research Site Letter(s) not required.
☐ Research Site Letter(s) attached.
☐ Research Site Letter(s) pending and will be provided when obtained.

17. Recruitment Method:

Describe how research participants will be recruited in the study. How will you identify potential participants? How will you contact them? **Attach a copy of any material you will use to recruit participants (e.g., advertisements, flyers, telephone scripts, verbal recruitment, cover letters, or follow-up reminders).**

Description: We plan to recruit through notices posted in the department and general announcements in class.

18. Participant Incentives:

a. Will you pay participants? ☐ Yes ☒ No

Amount: $_____ When will money be paid?: _____

b. Will you give participants incentives / gifts / reimbursements? ☐ Yes ☒ No

Describe incentives / gifts / reimbursements: _____

Value of incentives / gifts / reimbursements: $_____

When will incentives / gifts / reimbursements be given?: _____

c. Will participants receive course credit? ☐ Yes ☒ No

d. Will participants receive extra credit? ☐ Yes ☒ No
If YES, an equivalent alternative to research participation must be provided and described in your informed consent document(s).

19. Informed Consent:

***If all of your participants will be children**, please skip this question (19) and complete the Child Research Addendum (available here). If you will have both children and adults as participants in your study, please complete this question (for the adult participants) AND the Child Research Addendum (for the child participants).*

a. Will you use concealment or deception in this study? ☐ Yes ☒ No
If YES, please see guidance regarding Research Involving Deception or Concealment here, submit a copy of the Additional Pertinent Information / Permission for Use of Data Collected in a Research Study form you will use, and request a waiver of some elements of consent below [see 19(e)].

b. Do you plan to obtain informed consent from **all your adult research participants** (and / or legally authorized representatives for adult participants with diminished capacity)?
1) ☒ Yes ☐ No ☐ N/A
If YES, please skip to question 19(c).
Please submit all applicable Informed Consent documents with application (e.g., adult consent forms, informational letters, verbal consent scripts).
Consent Document Templates

If NO, please proceed with questions 19(b)(2)-19(b)(4) to request a **waiver of informed consent**.

If N/A, please explain and skip to question 20. _____

2) For what groups will you need this waiver of informed consent?
☐ for all participants ☐ for some participants (describe for which participants): _____

3) Please explain the need for the waiver. _____

4) As provided in 45 CFR 46.116(d), an IRB may waive the requirement for the investigator to obtain informed consent from research participants if it finds that all of the following criteria are met. Please explain how your study meets each of the criteria below:

Criteria for Waiver of Consent	**How is this criterion met within this study?**
The research involves no more than minimal risk to subjects.	
The waiver will not adversely affect the rights and welfare of the subjects.	
The research could not be carried out practicably without the waiver.	
Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.	

If you completed questions 19(b)(2)-19(b)(4) for **all adult research participants**, please skip to question 20.

c. Who will obtain the participants' consent? Check all that apply:

☐ Principal Investigator ☒ Co-Investigator ☐ Other Research Team Members

☐ Contracted / Hired Data Collection Firm: _____

☐ Other: _____

d. Will you collect participants' signatures on all consent documents?

1) ☐ Yes ☒ No
If YES, please skip to question 19(e).

If NO, please proceed with questions 19(d)(2)-19(d)(3) to request a **waiver of documentation (signature)**.

2) For what groups will you need this waiver of documentation?
☒ for all participants ☐ for some participants (describe for which participants): _____

3) As provided in 45 CFR 46.117(c), an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds that one of the following sets of criteria is met. Please check **ONE** box below to indicate which set of criteria is met by this study:

☐ That the research presents no more than minimal risk of harm to subjects and involves no procedure for which written consent is normally required outside of the research context.

☒ That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. If the subject wants documentation linking the subject with the research, the subject's wishes will govern.

e. Do you plan to use all of the consent elements in all your consent documents or procedures (see list below)?

1) ☒ Yes ☐ No
If YES, please skip to question 20.

If NO, please proceed with questions 19(e)(2)-19(e)(5) to request a **waiver of some elements of consent**.

2) For what groups will you need this waiver of some consent elements?
☐ for all participants ☐ for some participants (describe for which participants): _____

3) Please explain the need for the waiver request. _____

4) A list of consent elements is given below. Please indicate which of these elements you would like to have waived. (In the case of a study involving deception or concealment, the IRB must waive the requirement to use all elements that are not truthfully presented in the initial consent document.)

List of Elements of Informed Consent	
☐ participation involves research	☐ maintenance of confidentiality
☐ purposes of the research	☐ for more than minimal risk research, compensation / treatment available in case of injury
☐ duration of participation	
☐ procedures to be followed	☐ voluntariness of participation
☐ identification of experimental procedures	☐ no penalty for refusal to participate
	☐ may discontinue participation without penalty
☐ foreseeable risks / discomforts	☐ disposition of data already collected, upon withdrawal of participant
☐ benefits to subjects or others	
☐ appropriate alternatives advantageous to subject	☐ contact for questions about research
	☐ contact for questions about participants' rights

5) As provided in 45 CFR 46.116(d), an IRB may waive the requirement for the investigator to present all consent elements to participants if it finds that all of the following criteria are met. Please explain how your study meets each of the criteria below:

Criteria for Waiver of Elements of Consent	**How is this criterion met within this study?**
The research involves no more than minimal risk to subjects.	

The waiver will not adversely affect the rights and welfare of the subjects.	
The research could not be carried out practicably without the waiver.	
Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.	

Please make sure to submit all Informed Consent documents (i.e., adult consent forms, informa-tional letters, and / or verbal consent scripts) for which elements of consent are being waived.

20. Procedures:

a. What data will you collect? The study will objectively (by analyzing user eye tracking data) evaluate viewers' pupil diameter in a virtual environment. Users' eye information will be captured using a vive pro eye that is physically unobtrusive and is not associated with any risks apart from those encountered in normal computer use.

b. Please describe in detail the process each participant will experience and how you will obtain the data. Each participant will be greeted and briefed on the nature of the study using a script. They will then read an informational document approved by the Clemson University Institutional Review Board. Next, each participant will answer questions about their age and occupation. These along with their gender will be recorded with an assigned identification number. Participants will be allowed to ask researchers questions. They will then be given a brief demo of the experimental procedures inside of VR. They will then do the real study. Training will be simple and very similar to watching television.

c. How many participation sessions and how much time will be required for each participant, including follow-up sessions? 1 session per participant lasting approximately 30 minutes.

d. How will you collect data?
☒ in-person contact ☐ telephone
☐ snail mail ☐ email
☐ website ☐ other, describe _____

Please include copies of surveys, interview questions, data collection tools and debriefing statements. If survey or interview questions have not been fully developed, provide information on the types of questions to be asked, or a description of the parameters of the survey / interview. Please note: finalized survey or interview instruments will need to be reviewed and approved by amendment, before implementation.

e. Will you audio record participants? ☐ Yes ☒ No
f. Will you video record participants? ☐ Yes ☒ No
g. Will you photograph participants? ☐ Yes ☒ No

If you will audio or video record or take identifiable photographs of participants, please consult the IRB's Guidance on the Use of Audio / Video Recording and Photography here. Please include all the information addressed by this guidance document in the application and, where appropriate, in the consent document(s).

21. Protection of Confidentiality: Describe the security measures you will take to protect the confidentiality of the information obtained. Will participants be identifiable either by name or through demographic data? If yes, how will you protect the identity of the participants and their responses? Where will the data be stored and how will it be secured? Who will have access to the data? How will identifiers be maintained or destroyed after the study is completed?

Description: Participant names will not be recorded. Demographic data will be limited and used only in aggregate.

22. Risk / Benefit Analysis:

a. Describe all potential risks (before protective measures are put into place) and benefits for this study. Risks can include physical, psychological, social, legal or other risks connected with the proposed procedures. Benefits can include benefits to the participant or to society in general.

Description: There are minimal risks: eyestrain being the most serious. The experiment does not require anything more than wearing a head mounted display.

b. Describe the procedures to be used to protect against or minimize potential risks. Assess the likely effectiveness of these procedures.

Description: If, for any reason, participants become uncomfortable, they may quit the experiment, with no repercussions.

23. Agreement, Statement of Assurance, and Conflict of Interest Statement by the PI:

I have reviewed this research protocol and the consent form, if applicable. I have also evaluated the scientific merit and potential value of the proposed research study, as well as the plan for protecting human participants. I have read the Terms of Assurance held by Clemson University and commit to abiding by the provisions of the Assurance and the determinations of the IRB. I request approval of this research study by the IRB of Clemson University.

I understand that failure to adhere to any of these guidelines may result in immediate termination of the research. I also understand that approval of this research study is contingent upon my agreement to:

1. Report to the IRB any adverse events, research-related injuries or unexpected problems affecting the rights or safety of research participants (All such occurrences must be reported to the IRB within three (3) working days.);
2. Submit in writing for IRB approval any proposed revisions or amendments to this research study;
3. Submit timely continuing review reports of this research as requested by the IRB; and
4. Notify the IRB upon completion of this research study.

Conflict of Interest Statement:

Could the results of the study provide an actual or potential financial gain to you, a member of your family, or any of the co-investigators, or give the appearance of a potential conflict of interest?

☒ No.

☐ Yes. I agree to disclose any actual or potential conflict of interest prior to IRB action on this study.
Financial Conflict of Interest Policy for PHS / NIH Supported Research
Financial Disclosure Policy for All Other Sponsored Programs
Disclosure Statement for All Other Sponsored Programs

_____ _____

Signature of Principal Investigator Date

24. Statement of Assurance by Department Chair (or supervisor if PI is Department Chair):

I have reviewed this research protocol and the consent form, if applicable. I verify this proposed research study has received approval in accordance with department procedures. I have evaluated the plan for protecting human participants. I have read the Terms of Assurance held by Clemson University and commit to abiding by the provisions of the Assurance and the determinations of the IRB. I request approval of this research study by the IRB of Clemson University.

_____
Department Chair or supervisor if PI is Department Chair (Printed Name)

_____ _____
Signature of Department Chair Date

Submission Instructions:
Expedited applications are processed as received. There is no deadline for submitting expedited applications for review. Please allow three weeks for processing.

Full Board applications are accepted according to the schedule given here. Researchers are encouraged to attend the meeting at which their protocol will be reviewed, in order to be available to answer any questions IRB members might have about the protocol.

Please submit this application and all associated documents electronically to the IRB staff. In addition, please submit a signed, hard-copy of the application via mail or delivery to the Office of Research Compliance, 223 Brackett Hall, Clemson, SC 29634-5704. Alternatively, you may fax the signed copy to 864-656-4475 or scan and email to irb@clemson.edu.

Child (Minor) Research Addendum:
If your study involves children / minors as participants, click here to complete the Child Research Addendum**.** Once completed, please submit the Addendum with your Expedited / Full Board Review Application.

Prisoner (Incarcerated Individuals) Research Addendum:
If your study involves individuals who are incarcerated as participants, click here to complete the Prisoner Research Addendum**.** Once completed, please submit the Addendum with your Expedited / Full Board Review Application.