**IRB** **Expedited/Full Board Review Application**

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| Office use only | **Protocol Number:** |
| Approved:  Expedited: category  Full Board Review | Approval date:       Completion date: |

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| **1.** | **Developmental Approval:** Enter the IRB protocol number if developmental approval was granted for this research study (temporary approval granted by the IRB for funded projects). |

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| **2.** | **Research Title:** | CHS: Medium: Visual Gaze Analytics for Decision Making under Task Difficulty |
|  | If different, title used on consent document(s) |  |
|  | If class project, include course number and title |  |

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| **3.** | **Principal Investigator (PI):** The PI must be a [Clemson faculty or staff](http://www.clemson.edu/research/sponsored-programs/documents/pi-policy.pdf). Graduate students may not be the PI if they are conducting the study for their thesis or dissertation. The PI must have completed IRB approved [human research protections training](http://www.clemson.edu/research/compliance/irb/training.html). Training will be verified by IRB staff before approval is granted. | |
|  | Name: Andrew Duchowski | E-mail: duchowski@clemson.edu |
| Department: School of Computing | Phone: 656-7677 |
|  | Campus address: 309 McAdams | Faculty  Staff  Other: |

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| **4.** | **Co-Investigator(s):** Co-investigators not affiliated with Clemson University need IRB review at their home institution. IRB training required for all co-investigators listed on the protocol. [Additional team members](http://www.clemson.edu/research/compliance/irb/forms.html) form available on [IRB website](http://www.clemson.edu/research/compliance/irb/forms.html), under Expedited and Full Board review tabs. | | |
|  | Name: | | E-mail: |
|  | Department: | | Phone: |
|  | Faculty  Staff | Graduate student  Undergraduate student | Other: |
|  |  |  |  |
|  | Name: | | E-mail: |
|  | Department: | | Phone: |
|  | Faculty  Staff | Graduate student  Undergraduate student | Other: |

**5. Research Team Roles:** Describe team member’s role on the study, indicating which team member will be responsible for recruiting and/or collecting data.

**Description:** PI Duchowski is director of the eye tracking lab at Clemson's School of Computing and is responsible for human subjects protocol design and execution, data collection, and analysis. Additional team members will be added to the protocol via ammendments, when identfied.

**6. Email Communications:** Enter the name and e-mail address for co-investigator or administrative staff to be copied on all e-mail communications.

|  |  |
| --- | --- |
| Name: | E-mail: |
| Name: | E-mail: |

**7. Study Purpose:** Describe the purpose of the study using lay language and avoiding technical terms. IRB members not familiar with the area of research must understand the nature of the research.

**Description:** The purpose of the study is to estimate a person's workload from eye movements, e.g., by measuring pupil diameter and gaze position with an eye tracker while they perform mental tasks (e.g., memory "n-back" recall). Anonymized eye movement data will be processed to detect saccades and microsaccades. Results will be disseminated in the aggregate following analysis, e.g., as means of microsaccadic rate and magnitude, compared between conditions via statistical tests such as ANOVA.

**8.** **Benefits and Sharing of Results:** Describe the potential benefit(s) to the participants and/or society that may be reasonably expected as a result from this study.

**Description:** Benefits to society, if any, stem from applicability of research results to systems that can detect and respond to their users' workload. Such systems have the potential to improve both users' experiences and outcomes in many domains: students and teachers, drivers and pilots, rescue workers and soldiers might all benefit from systems that can detect when their jobs are too hard or easy and dynamically adapt the difficulty. Benefits to participants are likely minimal.

Upon conclusion of the study, describe how results will be shared (e.g., academic publication, evaluation report to funder, conference presentation)?

**Description:** Results of the study will be disseminated via academic publications, evaluation reports to funder, and conference presentatoins.

**9. Research Timeline:** Anticipated start date: Oct.02, 2018 Anticipated completion date: Jul.30, 2020

**10. Funding Source:** Please check all that apply.

Internally funded or submitted for internal funding: Describe:

Externally funded or submitted for external funding

Funding source (Do not use acronyms): National Science Foundation

Enter ten-digit proposal number (PPN) from the Office of Sponsored Programs: TBD

Name of PI on funding proposal: Andrew Duchowski

Not funded

**11. Support provided by Creative Inquiry Initiative:**  No  Yes

**12. Other IRB Approvals:**

Is this research study currently being reviewed or was approved by another IRB?  No  Yes

If YES, enter name of institution:       Determination Date:

Select status of review:  Approved  Disapproved  Pending

(Include determination notice/letter with IRB packet)

**13. Expedited Review Categories:** The Code of Federal Regulations, 55 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 provided** [**Decision Charts**](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html) **to assist with determining IRB review level.**

|  |  |
| --- | --- |
| 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. |

**14. Study Sample:** (Groups specifically targeted for study)

Describe the participants you plan to recruit and the criteria used in the selection process. Provide an explanation for any inclusion or exclusion criteria and describe screening process to determine eligibility (provide copy of screening tool).

**Description:** College students

Age range of participants: 18-24 Projected number of participants: 30

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Employees | Students | | Minors (under 18)2 |
|  |  |  | |  |
|  | Pregnant women1 | Fetuses/neonates1 | | Educationally/economically disadvantaged1 |
|  |  |  | |  |
|  | Minors who are wards of the state, or any other agency, institution, or entity1,2 | | | Individuals who are incarcerated3 |
|  |  |
|  | Persons incompetent to give valid consent1 |
|  |  | | |  |
|  | DoD personnel | | | Other-specify: |
|  |  | |  |  |

**1** State necessity for including this group:

**2** Research involving children (minors) requires submission of a [Child Research Addendum](http://www.clemson.edu/research/compliance/irb/forms.html) (under Expedited and Full Board Review tab).

**3** Research involving prisoners (incarcerated individuals) requires submission of a [Prisoner Research Addendum](http://www.clemson.edu/research/compliance/irb/forms.html).

**15. Study Locations:**

Clemson University  Other University / College

School System / Individual Schools        Other – specify

You may need permission if participants will be recruited on-site 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 documentation (signed letter or e-mail) from a person authorized to give you access to the participants or to the data. [Guidance regarding Research Site Letters](http://www.clemson.edu/research/compliance/irb/resources.html) is available on website.

Research Site Letter(s) not required.

Research Site Letter(s) attached.

Research Site Letter(s) pending and will be provided when obtained.

**16. Recruitment Procedures:** Describe how prospective participants will be contacted/recruited for the study and how contact information will be obtained. Include a copy of the recruitment materials in the packet (e.g., advertisements, flyers, oral and/or telephone scripts, cover letters, or follow-up reminders). Participants may not be contacted prior to IRB review.

**Description:** Email, posted recruitment flyer

**17. Participant Incentives:** Will participants receive any incentive or compensation for participating in the study?  No  Yes

If YES, check all that apply and provide requested information.

Course/extra credit for students (an equivalent alternative to research participation must be provided and described in your informed consent document(s).

Gift(s) - describe gift(s) [include value and when gift(s) will be given]:

Monetary incentive(s) - describe incentive(s) [include value and when incentive(s) will be given; partial payment offered]:

**18. Informed Consent from Adult Participants:**

If ALL of your participants will be minors, skip question (18) and complete the [Child Research Addendum](http://www.clemson.edu/research/compliance/irb/forms.html) (under Expedited or Full Board review tab). If you will have minors AND adults as participants in your study, complete this section for the adult participants AND the Child Research Addendum.

1. Will you use concealment or deception in this study?  No  Yes

If YES, see guidance regarding [Research Involving Deception or Concealment](http://www.clemson.edu/research/compliance/irb/resources.html), submit a copy of the [Additional Pertinent Information/Permission for Use of Data Collected in a Research Study](http://www.clemson.edu/research/compliance/irb/forms.html) form (under Expedited or Full Board review tab) you will use, and request a waiver of some elements of consent under question 18(d).

1. Do you plan to obtain informed consent fromALL of your adultresearch participants and/or legally authorized representatives for adult participants with diminished capacity?  No  Yes

If YES, describe the informed consent process, include who will obtain consent, when, and how this will be done.

**Description:** The PI will hand out an informational letter to each participant designed to obtain consent upon reading.

Provide a copy of the [informed consent document(s)](http://www.clemson.edu/research/compliance/irb/forms.html" \o "Consent Templates) (under Expedited or Full Board review tab): signed consent document, information letter, online script, and/or oral script. Skip to question 18(c)

If NO, answer questions 18(b)(1-2) to request a waiver of informed consent.

1. For what groups are you requesting a waiver of informed consent?

for all participants  for some participants (describe for which participants):      

1. As provided in 45 CFR 46.116(d), an IRB may waive the requirements to obtain informed consent if the following criteria are met. Explain how your study meets 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 are requesting a waiver of consent for ALL adult participants, then skip to question 19.

If you are requesting a waiver of consent for SOME adult participants, then complete questions 18c-d.

1. Will you collect participants’ signatures on all consent documents?  No  Yes

If YES, skip to question 18(d).

If NO, answer questions 18(c)(1-2) to request a waiver of signed consent.

1. For what groups are you requesting a waiver of signed consent?

for all participants  for some participants (describe for which participants):

1. As provided in 45 CFR 46.117(c), an IRB may waive the requirement for the PI to obtain a signed consent if one of the following criteria is met. Check one box below:

|  |  |
| --- | --- |
|  | 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. |

1. Do you plan to use all of the consent elements in your document(s) or procedures?  No  Yes

If YES, skip to question 19.

If NO, answer questions 18(d)(1-3) to request a waiver of some elements of consent.

1. For what groups are you requesting a waiver of some consent elements?

for all participants  for some participants (describe for which participants):

1. A list of consent elements is given below. Indicate which of these elements you will not include in your consent document(s) or procedures. In the case of a study involving deception or concealment, check all of the elements that are not truthfully presented during the informed consent process.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| List of Elements of Informed Consent | | | | | | |
|  | |  |  | | |  |
|  | participation involves research  purposes of the research  duration of participation  procedures to be followed  identification of experimental procedures  foreseeable risks/discomforts  benefits to participant or others  appropriate alternatives advantageous to participant | | |  | maintenance of confidentiality  for more than minimal risk research, compensation/treatment available in case of injury  voluntariness of participation  no penalty for refusal to participate or withdraw  disposition of data already collected, upon withdrawal of participant  contact for questions about research or participants’ rights | |
|  |  | | |  |  | |

1. As provided in 45 CFR 46.116(d), an IRB may approve a consent procedure which does not include some or all of the elements of informed consent if the following criteria are met. Please explain how your study meets 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. |  |

**19. Methods and Procedures:**

|  |  |
| --- | --- |
| a. | What data will you collect? Submit copy of data collection instruments/tools for review (i.e., surveys, interview questions).  **Description:** The study will collect demographic data (age, gender, eyesight, i.e., whether wearing corrective lenses) and eye movement data using a high-speed eye tracker. |
| b. | How will you collect the data?  In-person contact  Telephone  E-Mail  Mail  Online/website  Other - specify |
| c. | Will you audio/video record or photograph participants?  No  Yes  If YES, check all that apply:  Audio  Video  Photographs  If YES, will you use audio, video, or photographs in presentations, publications, and/or training materials?  No  Yes – a media release form is required  Refer to the [guidance on audio/video and/or photography](http://media.clemson.edu/research/compliance/irb/audio-video-tapes.pdf" \o "Audio/Video and Photo Guidance) for more information on what is required in the informed consent document or script. |

d. Describe, in detail, your data collection methods and procedures. Describe how data will be collected and what sessions will be audio/video recorded and/or photographed.

**Description:** Each participant will enter our eye tracking lab in McAdams hall. They will be presented with an informational letter and asked for consent to participate. They will then be seated in front of a typical computer monitor with an eye tracker mounted beneath. The eye tracker will be calibrated by having each participant look at a number of targets on the screen. They will then be asked to look at specific points on the screen identified by a marker or letter and will then be asked to simultaneously perform memory recall tasks.

1. What is the total time (hours, minutes, days) that each participant will spend in the entire study, include follow-up sessions?

**Description:** 1 session per participant lasting about 20 mins

1. Describe all potential risks (before protective measures are put into place). Risks may include possible loss of confidentiality, physical, psychological, social, legal or other risks connected with the proposed procedures.

**Description:** The only potential risk is fatigue and perhaps eye strain, and possible loss of confidentiality. Benefits, if any, stem from applicability of research results to systems that can detect and respond to their users' workload. Such systems have the potential to improve both users' experiences and outcomes in many domains: students and teachers, drivers and pilots, rescue workers and soldiers might all benefit from systems that can detect when their jobs are too hard or easy and dynamically adapt the difficulty.

1. Describe the procedures to protect against or minimize potential risks.

**Description:** Participants will be given rest breaks between stimuli. They may terminate the session at any time. Recorded data will be anonymized and stored in a password-protected server.

**20. Data Management Plan:**

1. Describe the security measures you will take to protect the confidentiality of the study records (including storage and who will have access to identifiable data, if applicable).

**Description:** No participant names will be stored; participants will be identified by number assigned to them. Anonymous data will be stored in a password-protected database. Data may be retained for future analysis.

1. How long will you retain identifiable data (i.e., contact information, audio/video recordings, photographs, digitized data)?

**Description:**

1. Will you use identifiable or de-identified data in future studies?  No  Yes
2. Will you share identifiable or de-identified data with funder, collaborators, or other researchers?

No  Yes

**21. Conflict of Interest Statement/Financial Disclosure:**

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 (COI)? Refer to [Conflict of Interest policy](http://www.clemson.edu/conflict-of-interest/) for more information.

No.

Yes; indicate the status of your COI and/or financial disclosure:

On file with COI office  Will be submitted to COI office

**22. PI Signature:**

Signature of the PI certifies that the information in the IRB packet is accurate and complete, PI is familiar with the [Federalwide Assurance for the Protection of Human Subjects](http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html#sectiona) held by Clemson University and institutional guidelines regarding human subjects research, and agrees to abide by the provisions of the Assurance and the determination of the IRB. The PI is responsible for assuring that all team members listed on the protocol are properly trained and adverse events, research-related injuries, or unexpected problems affecting the rights or safety of research participants are reported promptly to the [Office of Research Compliance](http://www.clemson.edu/research/compliance/irb/forms.html).

I understand that failure to adhere to any of these guidelines may result in immediate suspension or termination of the research.

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Signature of Principal Investigator Date

**23. Department Chair/Designee Signature (or supervisor if PI is Department Chair):**

Signature of the department chair or designee certifies that he/she is familiar with the project and the proposed research study is in compliance with the department’s policies and procedures.

Print Name of Department Chair or supervisor if PI is Department Chair

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Signature of Department Chair Date

**Submission Instructions:**

Please submit the IRB packet (application, recruitment materials, informed consent materials, and data collection instruments/tools) to [IRB@clemson.edu](mailto:IRB@clemson.edu). Signed copy of the IRB application may be sent electronically; hardcopy of the packet is not required.

**International research** – Review of international research may require additional time due to requirements in other countries, negotiation of Individual Investigator Agreements, arranging appropriate local context reviews, and geographical and communication constraints. Submit IRB application at least three to six months before your anticipated start date. More information on local context reviews is available on our FAQ webpage, <http://www.clemson.edu/research/compliance/irb/faq.html>. The [International Compilation of Human Research Standards](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html) is available on the Office of Human Research Protections (OHRP) webpage.

Current versions of the applications and templates are available on the IRB forms webpage, under the [Expedited and Full Board review tab.](http://www.clemson.edu/research/compliance/irb/forms.html)