**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. **Principal Investigator (PI):** The PI must be a Clemson faculty or staff, per the [PI assignment policy](http://www.clemson.edu/research/sponsored-programs/documents/pi-policy.pdf). Graduate students may not be the PI if they are conducting the research for their thesis or dissertation. The PI must have valid [human research protections training](http://www.clemson.edu/research/compliance/irb/training.html). | |
| Name: Duchowski, Andrew | E-mail: duchowski@clemson.edu |
| Department: School of Computing | Phone: 656-7677 |
| Campus address: 100 McAdams Hall | |
| Faculty  Staff  Other: | CITI expiration date: 16-Sep-2020 |

1. **Enter Project Title:** CPSC 4120/6120 Eye Tracking Methodology
2. **Research Personnel:** Will other individuals assist with recruiting, obtaining informed consent, data collection or data analysis?  No  Yes If YES, complete and attach the [Additional Research Team Members Form](http://www.clemson.edu/research/compliance/irb/forms.html).
3. **Study Purpose:** Describe the purpose and goals of the research using plain language (avoid technical terms, acronyms or jargon, unless explained).

**Description:** The purpose is for students conducting their course projects to run an eye-tracking experiment, where participants generally look at the computer screen while their gaze is recorded for subsequent analysis.

1. **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:** There are no known direct benefits that participants could reasonably expect other than perhaps becoming aware of eye-tracking technology and/or experimental procedures. Potential benefits to society include insight into how various stimuli (e.g., pictures) are viewed under varying conditions.

Describe how research results will be shared (e.g., academic publication, evaluation report to funder, conference presentation)?

**Description:** These are course projects which are generally not disseminated in any way.

1. **Research Timeline:** Anticipated start date: September 19, 2019 Anticipated completion date: December 11, 2019
2. **Funding:** Is the research funded (internal or external)?  No  Yes If YES, answer 7a-d.
3. Enter funding source (Do not use acronyms):
4. Enter name of PI on award:
5. Was the award processed through InfoEd?  No  Yes, enter ten-digit InfoEd proposal number (PPN):
6. Did the IRB office issue a developmental (temporary) approval for this research?  No  Yes, enter the IRB protocol number:
7. **Research Sites:** Will research activities occur at a non-Clemson site or outside of the United States?  No  Yes If YES, enter site location(s):

**Non-Clemson site(s):** Site permission may be required. Contact appropriate office/department **and include** site/support letter in IRB packet. If collecting data at another institution that has an IRB, you may need permission from each participating institution’s IRB office. See [Guidance on the Submission of Research Site/Permission Letters](http://media.clemson.edu/research/compliance/irb/research_site_letters.pdf) for more information.

**International projects:** Additional approval may be required. See [FAQs](http://www.clemson.edu/research/compliance/irb/faq.html) and [OHRP International Compilation of Human Research Standards](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html).

1. **Expedited Review Categories:** Select **one or more of the categories** below that appear to be applicable to your research.

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|  | 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. |

1. **Study Population**
2. Enter projected number of participants that will be enrolled in the study: 10 per study group
3. Identify the group(s) **specifically targeted** for the study (check all that apply).

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| Clemson students | Clemson faculty/staff |
| Adults not affiliated with Clemson | Minors, including wards of the state, or any other agency, institution, or entity (complete and attach [Child Research Addendum](http://www.clemson.edu/research/compliance/irb/forms.html)) |
| Non-English speaking individuals | Individuals with intellectual disabilities |
| Individuals with impaired decision-making capacity | Individuals economically or educationally disadvantaged |
| DoD personnel | Pregnant women |
| Prisoners (complete and attach [Prisoner Addendum](http://www.clemson.edu/research/compliance/irb/forms.html)) | Human Fetuses and/or Neonates |
| Other-describe: | |

1. **Recruitment Procedures**
2. Describe how potential participants will be identified and contacted: Email or recruitment flyer
3. Are there any inclusion or exclusion criteria for participation?  No  Yes If YES, describe criteria and screening process to determine eligibility (provide copy of screening tool) and briefly explain why the inclusion or exclusion criteria is necessary for your research:
4. Check all recruitment methods below **AND** **attach** copy of recruitment documents for review. See [Guidance for Recruitment Materials](http://media.clemson.edu/research/compliance/irb/recruitment-materials.pdf) for more information on what is required on the documents. Participants may not be contacted prior to IRB review.

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| Flyers/Advertisements | E-mail notice |
| In-person-describe: | Internet-describe: |
| Dept. subject pool-describe: | Letter mailed to individuals |
| Other-describe: | |

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

If YES, answer 12b-c.

1. Are there any conditions for receiving incentives (i.e., have to complete all research activities, answer attention check questions correctly)?  No  Yes If YES, describe conditions:
2. Check all that apply and provide requested information for each incentive checked (all incentives must be listed on informed consent document).

Course/extra credit for students (an equivalent alternative to research participation must be provided and described on informed consent document): Indicate number of credits that will be offered and if partial credits will be offered:

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

Monetary incentive(s): Indicate value of incentive, when incentive will be given and if partial payment will be offered:

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

**If ALL of your participants will be minors**, skip question 13 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. Do you plan to **obtain informed consent from ALL of your adult** research participants and/or legally authorized representatives for adult participants with diminished capacity?  No  Yes

If YES, skip to question to question 13b. If NO, answer questions 13(a)(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. The IRB may waive the requirements to obtain informed consent if the following criteria are met. Explain how your study meets the criteria below:

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| **Criteria for Waiver of Consent** | **How is this criterion met within this study?** |
| The research involves no more than minimal risk to subjects. |  |
| The research could not practicably be carried out without the requested waiver. |  |
| The waiver will not adversely affect the rights and welfare of the subjects. |  |
| Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. |  |
| If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. (Enter N/A if you are **NOT** recording identifiable data or collecting identifiable biospecimens.) |  |

If you are **requesting a waiver of consent for ALL** adult participants, then **skip to question 14**.

If you are **requesting a waiver of consent for SOME** adult participants, then **complete questions 13b-d**.

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

If YES, skip to question 13c. If NO, answer questions 13(b)(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. The 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:

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|  | 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. |
|  | If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. |

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 13d.

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

If YES, skip to question 14. If NO, answer questions 13(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.

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| **List of Elements of Informed Consent** | | | |
|  | statement that the study involves research |  | expected duration of participation |
|  | statement that participation is voluntary, refusal to participate or discontinue of participation will involve no penalty or loss of benefits |  | description of any reasonably foreseeable risks or discomforts |
|  | disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |  | description of any benefits to the participant or to others that may reasonably be expected from the research |
|  | explanation of the purposes of the research |  | statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained |
|  | description of the procedures to be followed |  | contact for answers to pertinent questions about the research and research subjects' rights |
|  | identification of any procedures that are experimental |  | **for more than minimal risk research**, compensation/treatment available in case of injury |

1. The 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:

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| **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 research could not practicably be carried out without the requested alteration. |  |
| The alteration will not adversely affect the rights and welfare of the subjects. |  |
| Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. |  |
| If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format. (Enter N/A if you are **NOT** recording identifiable data or collecting identifiable biospecimens.) |  |

1. **Research Methods and Procedures**
2. What data will you collect or devices/equipment will be used in the research? Check all that may apply **AND** **attach** copy of data collection instruments/tools (i.e., surveys, interview questions), photos of devices/equipment (i.e., eye tracker, activity trackers) and screenshots of mobile apps or computer programs.

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| Surveys/Questionnaires | Individual interview |
| Focus group | Observation |
| Student educational records ([FERPA](http://media.clemson.edu/research/compliance/irb/research-ferpa.pdf) may apply) | Protected Health Information ([HIPAA](https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html) may apply) |
| Digital data (i.e., computer, cell phone, other equipment/devices)-**describe**: eye tracker | X-ray, DEXA scan, or other device using ionizing radiation-**describe**: |
| Blood, urine or saliva-**describe**: | Drug, substances or biologics-**describe**: |
| Investigational medical device-**describe**: | Other-**describe**: |

1. Will you audio/video record or photograph participants?  No  Yes

If YES, check all that may 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

See [Guidance on the Use of Audio/Video Recording and Photographs](http://media.clemson.edu/research/compliance/irb/audio-video-tapes.pdf) for more information on what is required on the informed consent document.

1. Describe the informed consent process, include who will obtain consent from all participants, when, and how this will be done. If participants are not competent to consent for themselves, then describe procedures for obtaining consent from legally authorized representative. Attach all [informed consent document(s)](http://www.clemson.edu/research/compliance/irb/forms.html).

**Description:** Students will obtain consent by handing out informational letter at beginning of the procedure.

1. Describe, in detail, your data collection methods and procedures. Describe how data will be collected, what information will be collected from participants and what sessions will be audio/video recorded and/or photographed. Provide a timeline or schedule of events, if applicable.

**Description:** Data will be collected using a table-mounted (remote) Gazepoint GP3 eye tracker. Each pariticipant will be seated in front of a typical computer monitor with an eye tracker mounted underneath. The eye tracker will be calibrated by having each pariticipant look at a number of targets on the screen. They will then be asked to look at images and asked to perform some task, e.g., visual search.

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.

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.

1. **Data Management Plan:**
2. Will you collect biospecimens and/or information that could identity the participants directly or through identifiers linked to the participants (i.e., names, ID numbers, audio/video recordings and photographs, demographic data) during the study?  No  Yes

If NO, go to question 16.

If YES, answer 15b-d.

1. Describe your management plan for storing and securing the biospecimens and/or identifiable data, protecting the privacy of participants and maintaining confidentiality of biospecimens/data.

**Description:**

1. How long will you retain biospecimens and/or identifiable data (i.e., names, audio/video recordings, photographs, digitized data, codes or links to identifiers)?

**Description:**

1. Will you share biospecimens and/or identifiable data with other institutions, agencies, or companies?

No  Yes

**Describe management plan on informed consent document(s) and notify participants if biospecimens/data will be shared with other institutions, agencies, companies and/or used to support future studies.**

1. **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

1. **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

1. **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.

Victor Zordan

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

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Signature of Department Chair Date

**Submission Instructions:**

The PI has to 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)