Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (http://www.irb.vt.edu/pages/researchers.htm#conflict)

- [X] No
- [ ] Yes, explain:

1.2 WILL THIS RESEARCH INVOLVE COLLABORATION WITH ANOTHER INSTITUTION?

- [X] No, go to question 1.3
- [ ] Yes, answer questions within table

**IF YES**

Provide the name of the institution [for institutions located overseas, please also provide name of country]:

Indicate the status of this research project with the other institution’s IRB:

- [ ] Pending approval
- [ ] Approved
- [ ] Other institution does not have a human subject protections review board
- [ ] Other, explain:

Will the collaborating institution(s) be engaged in the research? (http://www.hhs.gov/ohrp/policy/engage08.html)

- [ ] No
- [ ] Yes

Will Virginia Tech’s IRB review all human subject research activities involved with this project?

- [ ] No, provide the name of the primary institution:
- [ ] Yes

*Note: primary institution = primary recipient of the grant or main coordinating center*

1.3 IS THIS RESEARCH FUNDED?

- [X] No, go to question 1.4
- [ ] Yes, answer questions within table

**IF YES**

Provide the name of the sponsor [if NIH, specify department]:

Is this project receiving federal funds?

- [ ] No
- [ ] Yes

If yes,
Does the grant application, OSP proposal, or “statement of work” related to this project include activities involving human subjects that are not covered within this IRB application?

- [ ] No, all human subject activities are covered in this IRB application
- [ ] Yes, however these activities will be covered in future VT IRB applications, these activities include:
  - [ ] Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows:
  - [ ] Yes, however these activities have been or will be reviewed by another institution’s IRB, the name of this institution is as follows:
  - [ ] Other, explain:

Is Virginia Tech the primary awardee or the coordinating center of this grant?

- [ ] No, provide the name of the primary institution:
- [ ] Yes

1.4 DOES THIS STUDY INVOLVE CONFIDENTIAL OR PROPRIETARY INFORMATION (OTHER THAN HUMAN SUBJECT CONFIDENTIAL INFORMATION), OR INFORMATION RESTRICTED FOR NATIONAL SECURITY OR OTHER REASONS BY A U.S. GOVERNMENT AGENCY?

For example – government / industry proprietary or confidential trade secret information

- [x] No
- [ ] Yes, describe:

1.5 DOES THIS STUDY INVOLVE SHIPPING ANY TANGIBLE ITEM, BIOLOGICAL OR SELECT AGENT OUTSIDE THE U.S?

- [x] No
- [ ] Yes

Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

This research project focuses on identifying whether the perceived size of common objects elicits differences in cognitive and cortical activity. Current theories of object recognition purport that recognition varies according to an objects structural properties, and that the structural properties of objects determines whether they are processed holistically or analytically. The problem under investigation involves determining how the perceived size of objects alters how their structural properties are processed by the visual system. Based on previous literature, we expect to find evidence that objects real-world physical size modulates how objects are visually perceived, as demonstrated by the presentation of objects at fixation on small and large displays at a constant retinal image size and patterned neural activity. Specifically, we expect to find that objects normally perceived analytically will be perceived more holistically when viewed on a large display due to an increased awareness of an objects global form and we also expect to find that objects normally perceived holistically will be perceived more analytically when viewed on a small display due to an increased awareness of an objects constituent parts. In association with these differences, we predict increased neural activity in the lateral occipito-temporal cortex during the presentation of holistic objects and increased neural activation in the area of the intraparietal sulcus during the presentation of analytical objects. Empirical studies of behavioral differences during the recognition of a wide range of real-world objects will enhance scientific models of human vision and object recognition processes.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

The results of this study will form the basis of a Master's thesis project. They will also be used to inform
Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:

Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

Subject pool (approx. 20 participants) will be representative of the Virginia Tech and Blacksburg communities. Exclusion for behavioral and fMRI participants will be based on visual acuity (must have normal or corrected-to-normal vision), handedness (limited to right-handed people only), age (must be at least 18 and no older than 40 years of age), and health status (must be healthy enough to participate in an MRI scan). Exclusion criteria for fMRI participants consists of the following: claustrophobia, history of head injury resulting in loss of consciousness for more than 10 minutes, and other contraindications to MRI (e.g. pacemaker, aneurysm clips, neurostimulators, cochlear implants, metal in eyes, steel worker, or other implants). All exclusion criteria will be assessed through self-report.

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?

Examples of existing records - directories, class roster, university records, educational records

☒ No, go to question 3.3

☐ Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
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<tbody>
<tr>
<td>Are these records private or public?</td>
</tr>
<tr>
<td>☐ Public</td>
</tr>
<tr>
<td>☒ Private, describe the researcher’s privilege to the records:</td>
</tr>
</tbody>
</table>

Will student, faculty, and/or staff records or contact information be requested from the University?

☐ No

☒ Yes, visit the following link for further information: [http://www.policies.vt.edu/index.php](http://www.policies.vt.edu/index.php) (policy no. 2010)

3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

Participants will be recruited through announcement flyers posted throughout the Virginia Tech campus, as well as through university, community, personal, and internet advertisements (posters, flyers, and classified ads).

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:

Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

The recruitment population was selected in order to provide a representative sample of the local and regional areas. Subject pool (approx. 20 participants) will be representative of the Virginia Tech and Blacksburg communities. The visual acuity requirement is necessary because participants will need to be able to see images on a computer display clearly in order to perform the task. Individuals older than 40 years will be excluded because this is the age after which individuals commonly need reading glasses or bifocals to remedy age-related far-sightedness (presbyopia). Far-sighted individuals could possibly experience eye fatigue if they were unable to wear their corrective glasses; the MRI-safe corrective lenses available for use at our MRI facility do not accommodate bifocals. Left-handed participants will be excluded because ample previous research has shown that one of the key phenomena targeted by this study (holistic perception effects) produces opposite MRI effects in left- versus right-handers. As a result, these...
groups' effects cancel each other out and produce false null effects in MRI data analyses. This study aims to describe the modal brain activity patterns of the general population, which are those of right-handers. Left-handers are relatively rare (approx. 10% of the general population), and rates of left-handedness are not strongly different across genders or ethnicities, so excluding left-handers is not likely to create such biases in the subject pool.

Section 4: Consent Process

For more information about consent process and consent forms visit the following link: [http://www.irb.vt.edu/pages/consent.htm](http://www.irb.vt.edu/pages/consent.htm)

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 CHECK ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY’S CONSENT PROCESS:

- ☒ Verbal consent will be obtained from participants
- ☒ Written/signed consent will be obtained from participants
- ☐ Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below)
- ☐ Other, describe:

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:

If possible, individuals who express interest in the study may be sent and asked to review a copy of the MRI safety screening form and the consent form before they arrive at a testing site to participate in the study. If the individual notes any contraindications to fMRI scanning, they will not be invited to take part in the experiment. However, even if the individual does not note any contraindications, this does not imply consent and they will again be asked to complete the screening form at the time of the fMRI experiment. The individual will also be instructed that they will need to review a copy of the consent form in the presence of the experimenter before participating in the study. That is, individuals will not be permitted to submit a signed version of the consent form that they have signed before arriving at the experiment site.

The participant will be given new copies of the MRI safety screening and consent forms and a verbal overview of their rights by the experimenter. This verbal overview will include their right to refuse consent and to withdraw at any time after consent is given. It will also include a review of the information to contact the experimenter or IRB in case of problems and a review of the risks and benefits of participation. The participant will then be asked to read the written consent form at their leisure and sign if they agree. If the participant expresses any distress during the experiment, the experimenter will remind the participant that they have the right to withdraw and end the experiment at any time.

4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?

The Principal Investigator, graduate student co-investigator, James Brown, and appropriately trained staff will oversee the consent process and will ensure that all subjects have been thoroughly briefed on the purpose of the study, potential value of the study to society, the lack of value to the subject personally, and all potential risks to the subjects. It will be the duty of the Principal Investigator and appropriately trained staff to make sure that all subjects are informed that he or she is under no obligation whatsoever to participate, and that if he or she wishes to discontinue their participation in the study at any time during the study, he or she is free to do so without penalty.
4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

At the experiment location (the Visual Neuroscience Laboratory, Room 234 Williams Hall and/or Building 26 of the Virginia Tech Corporate Research Center, Suite 2270).

4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR?

Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.

Informed consent will be obtained as soon as the participant arrives at the testing site, before any testing or data collection begins.

4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:

Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

Subjects will be encouraged to take their time and review the consent document before signing, and there will be ample time for subjects to do this and still complete the study within the total allotted time period.

☐ Not applicable

Section 5: Procedures

5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

Prior to the start of the experiment, participants will read and sign consent forms and will have all of the procedures explained by the experimenter. In the behavioral session of the experiment, participants will be seated in a chair in front of a computer screen throughout the task. Behavioral versions of the experiment will require between 30 minutes and 1 hour including paperwork and testing. Behavioral sessions of the experiment will take place in Williams Hall in the principal investigator's laboratory space where a comfortable chair and desk will be provided; or in a behavioral testing room outside of the MRI room in Building 26 of the Virginia Tech Corporate Research Center. Participants will use a chin rest and view pictures shown on a computer screen. They will be asked to name a variety of everyday objects by entering information using the keyboard. Then these objects will be presented on the screen briefly in random sequence at various locations in the peripheral field. The participant will be asked to verbally identify the object displayed. The accuracy and timing of subject responses will be analyzed to make inferences about mental processes.

The MRI session will be performed using general consent procedures described above. During the scanning session, participants will be shown brief, static images of the objects used in the behavioral study and asked to monitor changes in a fixation stimulus at the center of the screen. Participants will be instructed to press a button when they detect the change in the fixation stimulus. The entire scanning procedure is not expected to last longer than 1 hour. MRI versions of the experiment will take places at the VTCRI MRI imaging facilities in either Blacksburg or Roanoke.

MRI Scanning Procedure: After giving informed consent, the participant will fill out a standard screening questionnaire (attached) to make sure they can be safely included in the study. The participant will lay supine on the MRI table, with an RF coil placed over his/her head, and will be put into the center of the magnet. Participants will view the displays on a projection screen. The participant will be given a response box with which to indicate his/her responses. The exact timing will be controlled by a PC and linked to the MR imaging sequence. MRI data will be collected in runs of about 8 minutes long. In between runs, participants will be allowed to rest for at least one minute or until the participant indicates that they are ready to begin the next scan.

This protocol does not involve any contrast agents, drugs, or other invasive procedures, and uses established fMRI pulse sequences. Typical scan parameters are as follows:

- for EPI scans: gradient recalled echo, 34 slices in coronal or axial plane, slice thickness=3.4 mm, slice
5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

All data will be labeled with an arbitrary subject identifier (Sub1, Sub2, etc.) and no identifying information will be present in the data files.
Behavioral data will be collected using behavioral testing software (such as MATLAB and Psychophysics Toolbox) on desktop or laptop computers.
MRI data will be collected using the Siemens Advanced Development Workstation (an integrated part of the 3T Siemens Tim Trio system). Data will be exported to DVDs as backup immediately following each scan. Data will also be transferred via an intranet connection from VTCRI servers to computers in the principal investigator’s lab.

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITIES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)?

View the “Policy for Online Research Data Collection Activities Involving Human Subjects” at http://www.irb.vt.edu/documents/onlinepolicy.pdf

☐ No, go to question 6.1
☐ Yes, answer questions within table

IF YES

Identify the service / program that will be used:
☐ www.survey.vt.edu, go to question 6.1
☐ Blackboard, go to question 6.1
☐ Center for Survey Research, go to question 6.1
☐ Other

IF OTHER:
Name of service / program:
URL:
This service is…
☐ Included on the list found at: http://www.irb.vt.edu/pages/validated.htm
☐ Approved by VT IT Security
☐ An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages.
☐ None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

Potential risks in behavioral versions of the experiment are minimal. Participants may become bored during the procedure or may feel anxious about their performance on the task. In addition, participants may experience minor eye strain or fatigue from viewing images on the computer screen and/or feel slight discomfort after holding their chin in the chin rest for a sustained period of time.
An MRI scan is a painless radiology technique, which has the advantage of avoiding x-ray radiation exposure. There are no known side effects of an MRI scan.

The risks associated with fMRI are the same as those with conventional MRI. Movement or heating of metallic implants is a potential risk, and so subjects will be screened to exclude people with metallic implants, fragments, or pacemakers. Some individuals experience claustrophobic reactions in the scanner. Any subject experiencing claustrophobia will be removed from the scanner immediately.

The fMRI sequences produce loud noises which could be harmful to the subject. In order to protect participants we require all participants to wear sound attenuating ear protection.

There is no invasive component to this study, such as IV catheters, and so discomfort, bruising, or infection are not risks. The Siemens 3 T scanner has been approved by the FDA and the limits of RF energy that can be safely given to humans has been clearly defined by the FDA: a. The exposure to RF energy below the level of concern is an SAR of 0.4 W/kg or less averaged over the body, and 8.0 W/kg or less spatial peak in any 1 g of tissue, and 3.2 W/kg or less average over the head; or b. The exposure to RF energy that is sufficient to produce a core temperature increase of 1 degree C and localized heating to no greater extent than 38 degrees C in the head, 39 degrees C in the trunk, and 40 degrees C in the extremities, except for patients with impaired systemic blood flow and/or perspiration. We will adhere to the recommendations for the head. The scanner has a large monitor indicating the RF power level which can be limited to a specific maximum.

The subject may communicate with the experimenter at any time: 1) before, in between, or after a scan via an intercom device between the scanner and control room, and 2) during a scan via a pneumatic squeeze bulb located in the scanner that triggers an alarm in the control room. Subjects who report discomfort and wish to discontinue their participation will be immediately withdrawn from the scanner. Subjects who are withdrawn from the study will be compensated for their participation to that point.

6.2 EXPLAIN THE STUDY’S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

Participants will be given ample opportunities to take breaks and/or discontinue any version of the study if they become bored during the task. Participants will also be reassured that their performance falls within the normal range if they express anxiety regarding their task performance.

Visual stimuli will not be emotionally provocative or aversive. A reasonable number of trials will be performed to keep the study within approximately 1 hour to prevent boredom, discomfort, or eye strain.

MRI participants will be given a screening questionnaire (attached) prior to the study, which will allow us to identify persons who cannot be included in the study. The items in the questionnaire aim to identify any contraindications to the participant’s participation in the study with regards to their safety and comfort. All experimenters will receive extensive safety training regarding MRI procedures.

In order to protect the subject from potentially harmful MRI scanner noise, all subjects will be required to wear ear protection while in the scanner. The subject may communicate with the experimenter at any time: 1) before, in between, or after a scan via an intercom device between the scanner and control room, and 2) during a scan via a pneumatic squeeze bulb located in the scanner that triggers an alarm in the control room. Subjects who report discomfort and wish to discontinue their participation will be immediately withdrawn from the scanner. Subjects who are withdrawn from the study will be compensated for their participation to that point.

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

Benefits to participants are unlikely, aside from educational experience. The data collected from this experiment will be used to inform further research within the fields of visual cognition and neuroscience. It will be emphasized to the participants that the MRI scan is a research procedure, not a medical one, and so the scans will not provide the participants with any medically relevant information.

Section 7: Full Board Assessment
7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION?

☑ No
☐ Yes

7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR MENTALLY DISABLED PERSONS?

☑ No, go to question 7.3
☐ Yes, answer questions within table

IF YES

This research involves:
☐ Prisoners
☐ Pregnant women
☐ Fetuses
☐ Human in vitro fertilization
☐ Mentally disabled persons

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (http://www.irb.vt.edu/pages/categories.htm), it will not need to go to the Full Board.

☑ No
☐ Yes


Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link: http://www.irb.vt.edu/pages/confidentiality.htm

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

☑ No
☐ Yes, to whom will identifying data be released?

8.2 WILL ANY STUDY FILESContain PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

Note: if collecting signatures on a consent form, select “Yes.”

☑ No, go to question 8.3
☒ Yes, answer questions within table

IF YES

Describe if/how the study will utilize study codes: All paperwork and electronic files other than the
consent form will use a coded subject number that is arbitrary with respect to the participant’s identity. This code will be used to distinguish individual performance data.

<table>
<thead>
<tr>
<th>If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] be stored and who will have access? The document will be stored in a locked file cabinet separately from experiment data and questionnaires and only the PI and Co-Investigator will have access.</th>
</tr>
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<tbody>
<tr>
<td>Note: the key should be stored separately from subjects’ completed data documents and accessibility should be limited.</td>
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</table>

The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants. If you need to link subjects’ identifying information to subjects’ data documents, use a study ID/code on all data documents.

### 8.3 WHERE WILL DATA BE STORED?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

- All paper documents will be stored in a locked file cabinet. Electronic data will be identified using coded numbers only and will be stored on password-protected computers. No identifiable subject information will be stored electronically.

### 8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

- Only the principal investigator, co-investigator, and potentially future graduate students of the principal investigator, once they have completed human subjects and MRI training, will have access to study data.

### 8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING THE STUDY DATA

- Approximately 7 years after publication, paper data (the only identifiable participant information) may be destroyed by shredding the documents. Electronic data will be retained as long as space permits and if destroyed will be overwritten.

### 8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR?

- ✗ No, go to question 9.1
- ☐ Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
</tr>
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<tbody>
<tr>
<td>Does the study plan to obtain a Certificate of Confidentiality?</td>
</tr>
<tr>
<td>☐ No</td>
</tr>
<tr>
<td>☐ Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form)</td>
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</table>

For more information about Certificates of Confidentiality, visit the following link: [http://www.irb.vt.edu/pages/coc.htm](http://www.irb.vt.edu/pages/coc.htm)

### Section 9: Compensation

For more information about compensating subjects, visit the following link: [http://www.irb.vt.edu/pages/compensation.htm](http://www.irb.vt.edu/pages/compensation.htm)
9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION?

- No, go to question 10.1
- Yes, answer questions within table

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<th>IF YES</th>
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<tr>
<td>What is the amount of compensation? Paid participants will be compensated $25 per hour for both behavioral and neuroimaging studies.</td>
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</table>

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<tr>
<th>Will compensation be prorated?</th>
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<tbody>
<tr>
<td>Yes, please describe: Participants will receive compensation based on the hourly rate for that study with a minimum of one half hour of compensation.</td>
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</tbody>
</table>

- No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study?

Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must not be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link: [http://www.irb.vt.edu/pages/recordings.htm](http://www.irb.vt.edu/pages/recordings.htm)

10.1 WILL YOUR STUDY INVOLVE VIDEO AND/OR AUDIO RECORDING?

- No, go to question 11.1
- Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
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<tbody>
<tr>
<td>This project involves:</td>
</tr>
<tr>
<td>- Audio recordings only</td>
</tr>
<tr>
<td>- Video recordings only</td>
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<tr>
<td>- Both video and audio recordings</td>
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</table>

Provide compelling justification for the use of audio/video recording:

How will data within the recordings be retrieved / transcribed?

How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security?

Who will have access to the recordings?

Who will transcribe the recordings?

When will the recordings be erased / destroyed?

Section 11: Research Involving Students
11.1 DOES THIS PROJECT INCLUDE STUDENTS AS PARTICIPANTS?

- **No**, go to question 12.1
- **Yes**, answer questions within table

### IF YES

**Does this study involve conducting research with students of the researcher?**
- **No**
- **Yes**, describe safeguards the study will implement to protect against coercion or undue influence for participation:

  *Note: if it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so.*

**Will the study need to access student records (e.g., SAT, GPA, or GRE scores)?**
- **No**
- **Yes**

11.2 DOES THIS PROJECT INCLUDE ELEMENTARY, JUNIOR, OR HIGH SCHOOL STUDENTS?

- **No**, go to question 11.3
- **Yes**, answer questions within table

### IF YES

**Will study procedures be completed during school hours?**
- **No**
- **Yes**

  *If yes,*

  Students not included in the study may view other students’ involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome:

  Missing out on regular class time or seeing other students participate may influence a student’s decision to participate. Address how the study will reduce this outcome:

**Is the school’s approval letter(s) attached to this submission?**
- **Yes**
- **No**, project involves Montgomery County Public Schools (MCPS)
- **No**, explain why:

  *You will need to obtain school approval (if involving MCPS, click here: [http://www.irb.vt.edu/pages/mcps.htm](http://www.irb.vt.edu/pages/mcps.htm)). Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should accompany the approval request to the IRB.*

11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

- **No**, go to question 12.1
- **Yes**, answer questions within table
Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded:

- Included
- Actively excluded, describe how the study will ensure that minors will not be included: **Volunteers will be informed that they must be at least 18 years or older to participate. This age will be verified on the MRI screening form.**

### Will extra credit be offered to subjects?

- No
- Yes

If yes, what will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?

Include a description of the extra credit (e.g., amount) to be provided within question 9.1 (“IF YES” table)

### Section 12: Research Involving Minors

#### 12.1 DOES THIS PROJECT INVOLVE MINORS (UNDER THE AGE OF 18 IN VIRGINIA)?

*Note: age constituting a minor may differ in other States.*

- No, go to question 13.1
- Yes, answer questions within table

### IF YES

**Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide?**

- No
- Yes, thoroughly explain how the study will react to such reports:

*Note: subjects and parents must be fully informed of the fact that researchers must report threats of suicide or suspected/reported abuse to the appropriate authorities within the Confidentiality section of the Consent, Assent, and/or Permission documents.*

**Are you requesting a waiver of parental permission (i.e., parent uninformed of child’s involvement)?**

- No, both parents/guardians will provide their permission, if possible.
- No, only one parent/guardian will provide permission.
- Yes, describe below how your research meets all of the following criteria (A-D):
  - Criteria A - The research involves no more than minimal risk to the subjects:
  - Criteria B - The waiver will not adversely affect the rights and welfare of the subjects:
  - Criteria C - The research could not practicably be carried out without the waiver:
  - Criteria D - (Optional) Parents will be provided with additional pertinent information after participation:

**Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study?**

- No
- Yes, will the investigators seek and obtain the legally effective informed consent (in place of the minors’ previously provided assent and parents’ permission) for the now-adult subjects for any ongoing interactions with the subjects, or analysis of subjects’ data? If yes, explain how:
Section 13: Research Involving Deception

For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at http://www.irb.vt.edu/pages/deception.htm

13.1 DOES THIS PROJECT INVOLVE DECEPTION?

☑ No, go to question 14.1
☐ Yes, answer questions within table

IF YES

Describe the deception:

Why is the use of deception necessary for this project?

Describe the debriefing process:

Provide an explanation of how the study meets all the following criteria (A-D) for an alteration of consent:

Criteria A - The research involves no more than minimal risk to the subjects:
Criteria B - The alteration will not adversely affect the rights and welfare of the subjects:
Criteria C - The research could not practicably be carried out without the alteration:
Criteria D - (Optional) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception):

By nature, studies involving deception cannot provide subjects with a complete description of the study during the consent process; therefore, the IRB must allow (by granting an alteration of consent) a consent process which does not include, or which alters, some or all of the elements of informed consent.

The IRB requests that the researcher use the title “Information Sheet” instead of “Consent Form” on the document used to obtain subjects’ signatures to participate in the research. This will adequately reflect the fact that the subject cannot fully consent to the research without the researcher fully disclosing the true intent of the research.

Section 14: Research Involving Existing Data

14.1 WILL THIS PROJECT INVOLVE THE COLLECTION OR STUDY/ANALYSIS OF EXISTING DATA DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS?

☐ No, you are finished with the application
☐ Yes, answer questions within table
### IF YES

**From where does the existing data originate?**

**Provide a detailed description of the existing data that will be collected or studied/analyzed:**

**Is the source of the data public?**

- [ ] No, continue with the next question
- [ ] Yes, you are finished with this application

**Will any individual associated with this project (internal or external) have access to or be provided with existing data containing information which would enable the identification of subjects:**

- [ ] Directly (e.g., by name, phone number, address, email address, social security number, student ID number), or
- [ ] Indirectly through study codes even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc or
- [ ] Indirectly through the use of information that could reasonably be used in combination to identify an individual (e.g., demographics)

- [ ] No, collected/analyzed data will be completely de-identified
- [ ] Yes,

**If yes,**

Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected / analyzed, unless this requirement is waived by the IRB.

Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data? -select one-

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**This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.**

**Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.**

**Do not begin human subjects activities until you receive an IRB approval letter via email.**

**It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data.**