

**HRP-591 - Protocol for**

**Human Subject Research**

**Protocol Title:**

Provide the full title of the study as listed in item 1 on the “Basic Information” page in CATS IRB (<http://irb.psu.edu>).

Individual differences in visual perception in adults

**Principal Investigator:**

Name: Yiming Qian

Department: Department of Psychology

Telephone: (812)964-9865

E-mail Address: yxq5055@psu.edu

**Version Date:**

Provide the date of this submission. This date must be updated each time the submission is provided to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

2019-10-08

**Clinicaltrials.gov Registration #:**

Provide the registration number for this study, if applicable. See “HRP-103- Investigator Manual, When do I have to register my project at ClinicalTrials.gov?” for more information.

Not applicable.

**Important Instructions for Using This Protocol Template:**

This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

* + 1. **GENERAL INSTRUCTIONS:** 
       - Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
       - Do not change the protocol template version date located in the footer of this document.
       - Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
       - **GRAY INSTRUCTIONAL BOXES:**
* Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
* **Penn State College of Medicine/Penn State Health researchers**: Delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB (<http://irb.psu.edu>)**.**
* **Penn State researchers at all other campuses**: Do NOT delete the instructional boxes from the final version of the protocol.
* Add the completed protocol template to your study in CATS IRB (<http://irb.psu.edu>) on the “Basic Information” page.
  + 1. **CATS IRB LIBRARY:**
* Documents referenced in this protocol template (e.g. SOP’s, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (<http://irb.psu.edu>).
  + 1. **PROTOCOL REVISIONS:**
* When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (<http://irb.psu.edu>) for using track changes.
* Update the Version Date on page 1 each time revisions are made.

|  |  |
| --- | --- |
| **If you need help…** | |
| **University Park and other campuses:** [Office for Research Protections Human Research Protection Program](http://www.research.psu.edu/offices/orp/hrpp) The 330 Building, Suite 205 University Park, PA 16802-7014 Phone: 814-865-1775 Fax: 814-863-8699 Email: [irb-orp@psu.edu](mailto:ORProtections@psu.edu) | **College of Medicine and Penn State Health:** [Human Subjects Protection Office](http://www.pennstatehershey.org/web/irb) 90 Hope Drive, Mail Code A115, P.O. Box 855  Hershey, PA 17033  (Physical Office Location: Academic Support Building Room 1140) Phone: 717-531-5687 Email: [irb-hspo@psu.edu](mailto:irb-hspo@psu.edu) |

Table of Contents

[1.0 Objectives](#_Toc535504251)

[2.0 Background](#_Toc535504252)

[3.0 Inclusion and Exclusion Criteria](#_Toc535504253)

[4.0 Recruitment Methods](#_Toc535504254)

[5.0 Consent Process and Documentation](#_Toc535504255)

[6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization](#_Toc535504256)

[7.0 Study Design and Procedures](#_Toc535504257)

[8.0 Subject Numbers and Statistical Plan](#_Toc535504258)

[9.0 Data and Safety Monitoring Plan](#_Toc535504259)

[10.0 Risks](#_Toc535504260)

[11.0 Potential Benefits to Subjects and Others](#_Toc535504261)

[12.0 Sharing Results with Subjects](#_Toc535504262)

[13.0 Subject Payment and/or Travel Reimbursements](#_Toc535504263)

[14.0 Economic Burden to Subjects](#_Toc535504264)

[15.0 Resources Available](#_Toc535504265)

[16.0 Other Approvals](#_Toc535504266)

[17.0 Multi-Site Study](#_Toc535504267)

[18.0 Adverse Event Reporting](#_Toc535504268)

[19.0 Study Monitoring, Auditing and Inspecting](#_Toc535504269)

[20.0 Future Undetermined Research: Data and Specimen Banking](#_Toc535504270)

[21.0 References](#_Toc535504271)

[22.0 Confidentiality, Privacy and Data Management](#_Toc535504272)

# Objectives

## Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

This study investigates how human beings perceive visual motion in an experimental setting and how this ability is related to personal interests and other abilities. The results of this voluntary research study will help scientists gain a deeper understanding about what contributes to individual differences in motion perception, and whether and how motion perception correlates with other aspects in life.

## Primary Study Endpoints

State the primary endpoints to be measured in the study.

Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

The primary study endpoints are the completion of data collection for the proposed studies and the analysis of the collected data.

## Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

Not applicable at this moment.

# Background

## 

## Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

For clinical research studies being conducted at Penn State Health/Penn State College of Medicine, and for other non-PSH locations as applicable, describe the treatment/procedure that is considered standard of care (i.e., indicate how patients would be treated in non-investigational setting); and if applicable, indicate if the study procedure is available to patient without taking part in the study.

## 

Sex differences in interests and spatial and verbal abilities have long been studied. Recent studies (Wittmann & Szelag, 2003; Murray et al., 2018) have found that there are also sex differences in motion perception, one of the basic aspects of visual perception. Males have significantly better motion acuity, especially at higher spatial frequencies (Abramov, Gordon, Feldman & Chavarga, 2012). Females perceive time intervals longer than males do (Wittmann & Szelag, 2003), and males require shorter motion durations to perceive motion than females (Murray et al., 2018). Despite these intriguing results, relatively few researchers have investigated sex differences in motion processing, and so what underlies these differences or how they related to other sex differences in behavior remains unclear.

In the study proposed here, we will investigate how the four parameters found relevant in prior work (size, contrast, spatial frequency, and temporal frequency) contribute to sex differences in motion processing. We will extend the prior work by collecting larger samples that will enable the estimation of effects more precisely. We will also explore whether motion processing relates to other characteristics, such as personal interests and verbal and spatial abilities, where sex differences have been observed.

## Previous Data

Describe any relevant preliminary data.

The PI and Dr. Rick Gilmore have previously conducted a study on motion perception in children and adults (Qian, Seisler, & Gilmore, in prep). The results showed that males have better sensitivity than age-matched females in detecting complex patterns of motion.

## Study Rationale

Provide the scientific rationale for the research.

Visual perception, especially motion processing, may differ by sex. Understanding differences in motion processing may have important implications for understanding other sex differences. The goals of this study are to characterize whether and how males and females process motion information differently, and to explore how motion processing correlates with other behavioral attributes.

# Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.).

**Vulnerable Populations:**

Indicate specifically whether you will include any of the following vulnerable populations in this research. You MAY NOT include members of these populations as subjects in your research unless you indicate this in your inclusion criteria because specific regulations apply to studies that involve vulnerable populations.

The checklists referenced below outline the determinations to be made by the IRB when reviewing research involving these populations. Review the checklists as these will help to inform your responses throughout the remainder of the protocol.

* **Children –**Review “HRP-416- Checklist - Children”
* **Pregnant Women** – Review “HRP-412- Checklist - Pregnant Women”
* **Cognitively Impaired Adults-** Review “HRP-417- Checklist - Cognitively Impaired Adults”
* **Prisoners-** Review “HRP-415- Checklist - Prisoners”
* **Neonates of uncertain viability or non-viable neonates-** Review “HRP-413- Checklist - Non-Viable Neonates” or “HRP-414- Checklist - Neonates of Uncertain Viability”

[Do not type here]

## Inclusion Criteria

### Create a numbered list of the inclusion criteria that define who will be included in your final study sample (e.g., age, gender, condition, etc.)

College students (older than 18 years of age) who meet the following criteria will be included in the study.

1. who have normal or corrected-to-normal visual acuity, and don’t have visual problems such as strabismus (e.g., lazy eye) or cataract.
2. who didn’t experience serious medical problems at birth or shortly thereafter,
3. who don’t have any serious health problems currently.
4. who don’t have epilepsy or who have had seizures of any kind.

## Exclusion Criteria

### Create a numbered list of the exclusion criteria that define who will be excluded in your study.

We will exclude participants younger than 18 years of age. We will also exclude participants who experienced serious medical problems at birth or shortly thereafter, or who have had any serious health problems currently. We will exclude participants who have visual problems such as strabismus (e.g., lazy eye) or cataract. We will exclude participants who have epilepsy or who have had seizures of any kind.

## Early Withdrawal of Subjects

### Criteria for removal from study

### Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

Participants may be withdrawn from the study if they fail to consent to the procedures, fail to maintain attention during the visual tests or otherwise fail to adhere to the protocol requirements.

### Follow-up for withdrawn subjects

### Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

There will be no follow-up for withdrawn subjects.

# Recruitment Methods

* + - Upload recruitment materials for your study in CATS IRB (<http://irb.psu.edu>). **DO NOT** include the actual recruitment wording in this protocol.
    - StudyFinder: If StudyFinder (<http://studyfinder.psu.edu>) is to be used for recruitment purposes, separate recruitment documents do not need to be uploaded in CATS IRB. The necessary information will be captured from the StudyFinder page in your CATS IRB study.
    - Any eligibility screening questions (verbal/phone scripts, email, etc.) used when contacting potential participants must be uploaded to your study in CATS IRB (<http://irb.psu.edu>).

[Do not type here]

## Identification of subjects

Describe the source of subjects and the methods that will be used to identify potential subjects (e.g., organizational listservs, established recruitment databases, subject pools, medical or school records, interactions during a clinic visit, etc.). If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder:

* + If you intend to use StudyFinder (<http://studyfinder.psu.edu>) for recruitment purposes, include this method in this section.
  + Information provided in this protocol needs to be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Health submissions using Enterprise Information Management (EIM) for recruitment, and for non-Hershey locations as applicable, attach your EIM Design Specification form on in CATS IRB (<http://irb.psu.edu>). See “HRP-103- Investigator Manual, What is appropriate for study recruitment?” for additional information. **DO NOT** include the actual recruitment material or wording in this protocol.

Adult participants will come from the Psychology Department's Subject pool at University Park ([https://pennstate.sona-systems.com](https://pennstate.sona-systems.com/)). These individuals will self-identify as research participants by signing up for a study on the participant pool web page.

## Recruitment process

Describe how potential subjects first learn about this research opportunity or indicate as not applicable if subjects will not be prospectively recruited to participant in the research. Subject recruitment can involve various methods (e.g., approaching potential subjects in person, contacting potential subjects via email, letters, telephone, ResearchMatch, or advertising to a general public via flyers, websites, StudyFinder, newspaper, television, and radio etc.). **DO NOT** include the actual recruitment material or wording in this protocol.

[Do not type here]

### How potential subjects will be recruited.

Adult participants will be recruited from the Psychology Department participant pool, in accordance with the guidelines for the use of the pool:

1. An announcement describing the study will be posted on-line, along with available testing times in blocks of 1 hour.
2. The announcement will specify the exclusionary criteria as indicated in the section below.
3. Participants will sign-up for scheduled sessions using the participant pool calendar/scheduling system.

### Where potential subjects will be recruited.

From the Psychology Department participant pool ([https://pennstate.sona-systems.com](https://pennstate.sona-systems.com/)).

### When potential subjects will be recruited.

Potential subjects will be recruited throughout the fall semester of 2019 calendar year. The recruitment may be extended to the spring semester, depending on the fulfillment of the expected sample size.

* + - 1. Describe the eligibility screening process and indicate whether the screening process will occur before or after obtaining informed consent. Screening begins when the investigator obtains information about or from a prospective participant in order to determine their eligibility. In some studies, these procedures may not take place unless HIPAA Authorization is obtained OR a waiver of HIPAA Authorization when applicable for the screening procedures is approved by the IRB. [*For FDA regulated studies, consent for any screening activities would need to be obtained prior to screening unless specifically waived by the IRB.]*

The Psychology Subject Pool ([https://pennstate.sona-systems.com](https://pennstate.sona-systems.com/)) will be used to recruit adult participants from the participant pool will indicate that only healthy individuals with normal or corrected-to-normal vision, and no history of epilepsy or seizures will be permitted to participate. If the participants indicate that they fall into one of the excluded categories, they will be told they cannot participate in the study.

# Consent Process and Documentation

Refer to the following materials:

* The “HRP-090- SOP - Informed Consent Process for Research” outlines the process for obtaining informed consent.
* The “HRP-091– SOP - Written Documentation of Consent” describes how the consent process will be documented.
* The “HRP-314- Worksheet - Criteria for Approval” section 7 lists the required elements of consent.
* The “HRP-312- Worksheet - Exemption Determination” includes information on requirements for the consent process for exempt research. In addition, the CATS IRB Library contains consent guidance and templates for exempt research.
* The CATS IRB library contains various consent templates for expedited or full review research that are designed to include the required information.
* Add the consent document(s) to your study in CATS IRB (<http://irb.psu.edu>). Links to Penn State’s consent templates are available in the same location where they are uploaded. **DO NOT** include the actual consent wording in this protocol.

[Do not type here]

## Consent Process:

**Check all applicable boxes below:**

**Informed consent will be sought and documented with a written consent form *[Complete Sections 5.2 and 5.6]***

**Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) *[Complete Sections 5.2, 5.3 and 5.6]***

**Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). *[Complete section 5.2, 5.4 and 5.6]***

**Informed consent will not be obtained – request to completely waive the informed consent requirement. *[Complete Section 5.5]***

**The following checkbox is for all locations EXCEPT Penn State Health and College of Medicine:**

**Exempt Research at all Locations Except Penn State Health and the College of Medicine: If you believe that the research activities outlined meet one or more of the criteria outlined in “HRP-312- Worksheet- Exemption Determination.” Please verify by checking this box that if conducting an exempt research study, the consent process will disclose the following (all of which are included in “HRP-590- Consent Guidance for Exempt Research”):**

Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; and subjects may choose not to answer specific questions.

**If the research includes the use of student educational records include the following language in this section (otherwise delete):**

**Note: If this box has been checked, skip the remainder of section 5 and proceed to section 6 of this protocol. If the investigator’s assessment is inaccurate, an IRB Analyst will request revision to the protocol and that an informed consent form be submitted for review and approval. Except for exemptions where Limited IRB Review (see “HRP-312- Worksheet- Exemption Determination”) is required or where otherwise requested by the IRB, informed consent forms for research activities determined to be exempt without Limited IRB Review are generally not required to be submitted for review and approval by the University Park IRB.**

## Obtaining Informed Consent

### Timing and Location of Consent

Describe where and when the consent process will take place.

Consent will be obtained at the scheduled testing appointment time at the laboratory in 503 Moore building. There, an experimenter will explain the nature of the study and obtain informed consent or assent.

### Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

In the laboratory located in 503 Moore building on the day of his or her appointment, participants are given a written consent form to read. Also, in order to minimize the possibility of coercion and undue influence due to issues of communication, IRB-approved personnel will also read aloud from a script that describes the details of the study and procedures using layperson's terms. Participants need to consent to it verbally. Participants will be reminded during the consent process that participation is completely voluntary.

## Waiver of Written Documentation of Consent

Review “HRP – 411 – Checklist – Waiver of Written Documentation of Consent.”

### Indicate which of the following conditions applies to this research:

The research presents no more that minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*

OR

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. (*Note: This condition is not applicable for FDA-regulated research.)*

Describe the alternative mechanism for documenting that informed consent was obtained:

Verbal script and implied consent form

### Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, implied consent form, or summary explanation of the research)

An implied consent form will be used to inform participants about the research. Also, IRB-approved personnel will also read aloud from a script that describes the details of the study and procedures using layperson's terms. Participants need to verbally consent to it.

## Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

Review “HRP-410-Checklist -Waiver or Alteration of Consent Process” to ensure that you have provided sufficient information.

### Indicate the elements of informed consent to be omitted or altered

[Type protocol text here]

### Indicate why the research could not practicably be carried out without the omission or alteration of consent elements

[Type protocol text here]

### Describe why the research involves no more than minimal risk to subjects.

[Type protocol text here]

### Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

[Type protocol text here]

### If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

[Type protocol text here]

### Debriefing

Explain whether and how subjects will be debriefed after participation in the study. If subjects will not be debriefed, provide a justification for not doing so. Add any debriefing materials to the study in CATS IRB.

[Type protocol text here]

## Informed consent will not be obtained – request to completely waive the informed consent requirement

Review “HRP-410-Checklist -Waiver or Alteration of Consent Process” to ensure that you have provided sufficient information.

### Indicate why the research could not practicably be carried out without the waiver of consent

[Type protocol text here]

### Describe why the research involves no more than minimal risk to subjects.

[Type protocol text here]

### Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

[Type protocol text here]

### If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

[Type protocol text here]

### Additional pertinent information after participation

Explain if subjects will be provided with additional pertinent information after participation. If not applicable, indicate “not applicable.”

[Type protocol text here or indicate as not applicable]

## Consent – Other Considerations

### Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review “HRP-091 –SOP- Written Documentation of Consent” and “HRP-103 -Investigator Manual” to ensure that you have provided sufficient information.

Not applicable. We do not plan to recruit participants who can not speak English.

### Cognitively Impaired Adults

Refer “HRP-417 -CHECKLIST- Cognitively Impaired Adults” for information about research involving cognitively impaired adults as subjects.

#### Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

The adults we intend to recruit will come from the undergraduate Psychology Subject Pool. We will require that participants be 18 years of age or older in order to participate.

#### Adults Unable to Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual’s authority to consent to research.

For research conducted in the state of Pennsylvania, review “HRP-013 -SOP- Legally Authorized Representatives, Children and Guardians” to be aware of which individuals in the state of Pennsylvania meet the definition of “legally authorized representative.”

For research conducted outside of the state of Pennsylvania, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “HRP-013 -SOP- Legally Authorized Representatives, Children, and Guardians.”

Research staff who have concerns about whether an individual has that capability at the time of testing will be advised not to proceed with the testing session and to consult with the co-PI, Dr. Gilmore, thereafter.

##### Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

We will not test adults who cannot give consent.

### Subjects who are not yet adults (infants, children, teenagers)

#### 

#### Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual’s authority to consent to each child’s general medical care.

For research conducted in the state of Pennsylvania, review “HRP-013-SOP- Legally Authorized Representatives, Children and Guardians” to be aware of which individuals in the state of Pennsylvania meet the definition of “children.”

For research conducted outside of the state of Pennsylvania, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “HRP-013-SOP- Legally Authorized Representatives, Children, and Guardians.”

We will not test participants who are under the age of 18.

#### Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

We will not test participants who are under the age of 18.

# HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See “HRP-103 -Investigator Manual” for a list of the 18 identifiers.

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

[Do not type here]

## Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

**Check all that apply:**

**Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

**Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

**Partial waiver is requested for recruitment purposes only (Check this box if patients’ medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

**Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

**Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

## Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

### Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

#### Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. **If the section is not applicable, remove the statement and indicate as not applicable.**

*Information is included in the “Confidentiality, Privacy and Data Management” section of this protocol.*

#### Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

[Type protocol text here]

### Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

[Type protocol text here]

### Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alternation of authorization.

[Type protocol text here]

## Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver or alteration of authorization. **If the section is not applicable, remove the statement and indicate as not applicable.**

*Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.*

*The research team will collect only information essential to the study and in accord with the ‘Minimum Necessary’ standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.*

*Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.*

# Study Design and Procedures

Data collection materials that will be seen or used by subjects in your study must be uploaded to CATS IRB (<http://irb.psu.edu>). **DO NOT** include any actual data collection materials in this protocol (e.g., actual survey or interview questions)

[Do not type here]

## Study Design

Describe and explain the study design.

The study design requires one visit per participant. An individual will participate in the procedures outlined in 7.2 and 7.2.1 during a single visit.

## Study Procedures

Provide a step by step description of all research procedures being conducted (broken down by visit, if applicable) including such information as below (where and when applicable); describe the following:

* HOW: (e.g., data collection via interviews, focus groups, forms such as surveys and questionnaires, medical/school records, audio/video/digital recordings, photographs, EKG procedures, MRI, mobile devices such as electronic tablets/cell phones, observations, collection of specimens, experimental drug/device testing, manipulation of behavior/use of deception, computer games, etc.)
* WHERE: (e.g., classrooms, labs, internet/online, places of business, medical settings, public spaces, etc.)

The study will be conducted in 503 Moore. Once informed consent has been obtained, participants will be asked to have a visual acuity test, provide demographic information, and then complete computer-based surveys and computerized behavioral tests.

### Visit 1 or Day 1 or Pre-test, etc.

Provide a description of what procedures will be performed on visit 1 or day 1 or pre-test in order of how these will be done. If your study only involves one session or visit, use this section only and indicate 7.2.2 as not applicable.

The experimental procedures include a visual acuity test, computer-based surveys and behavioral tests.

Visual Acuity Testing

We use the Snellen Optotype Acuity chart similar to those seen in most optometry facilities. Participants are asked to read aloud, row by row, the letters they see on the chart. These measures aid the interpretation of possible outliers during future data analysis. All performance data is recorded silently by the experimenter, and no indication of performance is provided to the participant. Color Vision test and Stereo Acuity test may be added to supplement visual acuity testing.

Demographic Information

Demographic information for each participant will be collected using the form ‘participant\_demographics.docx’. The requested data consists of age in years, gender, current year in school, and major.

Computer-based (Qualtrics) surveys

Once informed consent has been obtained and pre-testing has been completed, the researcher will accompany the participant to one of the testing chambers within 503 Moore. The participants will be asked to complete the hobbies questionnaire (Lippa & Connelly, 1991), a test of spatial ability (Vandenberg & Kuse, 1978), and a test of verbal ability (Ekstrom, French, Harman, 1976).

Computerized behavioral tests

In the 503 Moore suite, participants will be seated on a chair in front of a computer monitor and placed a specified distance from the monitor, typically 60cm. The researcher will review with the participant the nature of the task and will ask the participant if he or she has any questions prior to proceeding with the study. If the participant agrees, the researcher starts the computer program that controls the visual display presentation.

Once the experimenter begins the display, the stimuli will appear and begin varying according to the frequency and other parameters set by the experimenter. During a trial, participants may be asked to maintain fixation on a central fixation cross. For adults, we may test 4-8 conditions with up to 50 trials each per condition. The order of testing is usually random.

For illustrative purposes, the following sections describe the two main types of displays that will be presented in different conditions of the study.

a. Contrast sensitivity paradigm.

Contrast sensitivity refers to the smallest difference between dark and light striped areas that an individual can discern at a given stripe width. Generally speaking, adults are most sensitive to low contrast at middle stripe widths (spatial frequencies), and sensitivity falls off as stripes get wider or narrower.

To assess contrast sensitivity, black and white stripes are presented to the participant in a time-varying way, such that the stripes appear or disappear against a gray background. A staircase experimental design is used in which the contrast or difference in luminance between the black and white bars goes from high to low or low to high across a trial with the spatial frequency held constant.

This test is a replication and extension of Abramov and his colleagues’ study (2012). The PIs plan to use sinusoidal gratings whose Michelson contrasts (luminances: ((max-min)/(max+min)) vary from near zero to near 40%; see Fig.1). Several conditions of grating with the spatial frequency in a range of 1.2 - 12 cycle/deg and temporal frequency (for example, 1 Hz). The final threshold of 80% correct performance will be obtained using a two-alternative forced-choice procedure – on each trial, the participants choose whether the grating is horizontal or vertical. The sinusoidal grating will be “ramped” on and off for 0.5s and kept at full contrast for 1s. The trials are self-paced, which means the participant starts the next trial when they are ready.

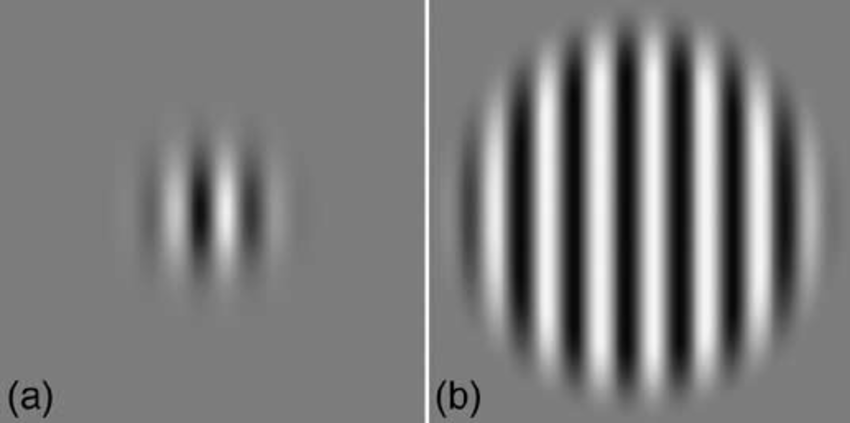


Fig 1. The grating stimuli in the display

b. Motion duration threshold test

Motion duration threshold refers to the minimum amount of time an individual needs to accurately perceive motion direction.

We will extend the approach taken previously (Murray et al., 2018) that used time-limited grating-based stimuli to estimate motion duration thresholds. In each trial, a drifting sinusoidal luminance modulation grating will be displayed in the center of the screen and move in one of 2 possible directions in a randomized order (left or right, see Fig.1). Temporal envelopes are trapezoidal, with the duration defined by the full-width at half-maximum contrast of the temporal envelope. There will be 2 different Michelson contrast levels (for example 3 % and 98%) and 2 different sizes (for example 2and 12). Motion speeds will be in the range of 1-10 cycles/s and spatial frequency will be in the range of 1-24 cycles/.

The grating stimuli will appear for short (16 – 333 ms) variable durations that are controlled by a computer-controlled staircase procedure, then followed by another blank screen (150 ms), and finally a fixation mark (the response cue). Participants need to press the left or right key. A staircase procedure will be applied with a criterion of 80% correct.

c. After the computer-based testing

Once the experiment has ended or the experimenter has terminated the testing, the participant will be escorted to the waiting area in 503 Moore. Arrangements for granting course credit will then be made.

Following the participant’s departure, the surfaces (keyboards, desks) will be cleaned and disinfected with disposable wipes and electronic data files will be saved and stored safely.

### Visit 2 or Day 2 or Post-test, etc. (If applicable)

Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.).

Not applicable

## Duration of Participation

Describe how long subjects will be involved in this research study. Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

The typical participant visits the lab one time for about an hour. There are two segments in total. The first one consists of computer-based (Qualtrics) surveys which take about 25 minutes. The second segment consists of computerized behavioral tests, which take about 25 minutes.

# Subject Numbers and Statistical Plan

## Number of Subjects

## Indicate the maximum number of subjects to be accrued/enrolled. Distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures if applicable (i.e., numbers of subjects excluding screen failures.)

The expected number of subjects to be enrolled and screened is 300. We expect to test 300 participants to complete the studies envisioned here. This takes into account 10-20% loss due to screening failures, equipment failures, and data loss.

## Sample size determination

If applicable, provide a justification of the sample size outlined in section 8.1 to include reflections on, or calculations of, the power of the study.

A total of 300 participants will be recruited for the study. This was based on the results from prior studies where medium to large effect sizes were observed and includes a number needed to correct for multiple statistical comparisons.

## Statistical methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

Correlation

We will conduct a correlation test with behavioral data and survey items to check whether there is correlation between motion performance, hobbies, verbal and spatial ability.

Regression model

We will fit a multiple regression model with behavioral data and survey items, to investigate the relationship between motion performance (duration and contrast thresholds) and majors, sex, age, and hobbies.

# Data and Safety Monitoring Plan

**This section is required when research involves more than Minimal Risk to subjects as defined in “HRP-001 SOP- Definitions.”**

Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

**Please complete the sections below if the research involves more than minimal risk to subjects, otherwise indicate each section as not applicable.**

[Do not type here]

## Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Not applicable.

* 1. **Data that are reviewed**

## Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

Not applicable.

## Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

Not applicable.

## Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

Not applicable.

## Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Not applicable.

## Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

Not applicable.

## Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

Not applicable.

## Suspension of research

Describe any conditions that trigger an immediate suspension of research.

Not applicable.

# Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration and reversibility of the risks. Consider all types of risk including physical, psychological, social, legal, and economic risks. Note: Loss of confidentiality is a potential risk when conducting human subject research.

* If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
* If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
* If applicable, describe risks to others who are not subjects.

There are no foreseeable risks associated with this study, although staring at visual stimuli on a computer screen in the dark room may cause participants some boredom or mild discomfort. To minimize even these small risks, participants do not have to answer any questions they do not wish to answer, and we will provide breaks throughout the testing. Additionally, there is a risk of loss of confidentiality concerning the data participants provide, but precautions will be taken to prevent this from happening. Information participants provide will only be seen by the personnel related to this research.

# Potential Benefits to Subjects and Others

## Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 13.0.

We cannot promise any benefits to participants from taking part in this study. However, the possible direct benefit of this research to participants is that they may have the chance to learn more about psychological research.

## Potential Benefits to Others

Include benefits to society or others.

The results of the study may benefit other people in the future by helping us learn more about the range of motion perception in adults.

# Sharing Results with Subjects

## Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how information will be shared.

# 

Group/study, but not individual-level results will be shared with participants and the public via our laboratory website (http://gilmore-lab.github.io) and published presentations and journal articles.

# Subject Payment and/or Travel Reimbursements

Describe the amount, type (cash, check, gift card, other) and timing of any subject payment or travel reimbursement. If there is **no** subject payment or travel reimbursement, indicate as not applicable.

Extra or Course Credit: Describe the amount of credit **and** the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered. It is not acceptable to indicate that the amount of credit is to be determined or at the discretion of the instructor of the course.

Approved Subject Pool: Indicate which approved subject pool will be used; include in response below that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

Psychology Department Subject Pool adult participants will receive one hour of participation credit. Online tutorials are provided via the Psychology Department Subject Pool website as a research alternative for students who are minors or conscientious objectors to obtain course credit. Tutorials are expected to require one hour of the participant's time per credit earned. Several tutorials are provided on the Subject Pool website, so participants have the option to choose the material on which they will be tested.

# Economic Burden to Subjects

## Costs

Describe any costs that subjects may be responsible for because of participation in the research.

## 

Participants will be responsible for transportation costs to and from the laboratory.

## Compensation for research-related injury

**If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.**

**If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:**

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

**For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written -** **DO NOT ALTER OR DELETE:**

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

# Resources Available

## 

## Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator’s experience conducting research at these locations and familiarity with local culture.

## 

The study will occur in 503 Moore, a medium-sized research room with one separate small testing chamber located adjacent to it.

## Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

Based on prior recruiting efforts in our lab group, it may be a challenge to recruit the required number of participants quickly, but the studies are not time-locked.

## PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

The PI will devote 1 academic semester plus several additional academic year months.

## Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subjects might need as a result of their participation in the study, if applicable.

Participants may contact the research protection advocate in the Office for Research Protections at 814-865-1775 if they:

* Have questions regarding your rights as a person in a research study.
* Have concerns, complaints or general questions about the research.
* Have questions about your privacy and the use of your personal health information.
* You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

## Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

New team members undergo extensive training. First, all members must complete CITI ethics training and share their completion certificate with the PI and co-PI. Second, all members must review this protocol. Next, all team members undergo hands-on training with the equipment under the supervision of a senior graduate student, lab staff member, co-PI, or the PI. Finally, lab staff observe and assist with data collection sessions under the supervision of a senior staff member.

Lab staff review protocols and discuss data collection issues during weekly staff meetings.

# Other Approvals

## Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from engaged cooperating institutions IRBs who are also reviewing the research and other required review committees, community leaders, schools, research locations where research is to be conducted by the Penn State investigator, funding agencies, etc.).

Not applicable.

## Internal PSU Committee Approvals

**Check all that apply:**

Anatomic Pathology – **Penn State** Health **only** – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of “HRP-902 - Human Tissue For Research Form” in CATS IRB.

Animal Care and Use – **All campuses** – Human research involves animals and humans or the use of human tissues in animals

Biosafety – **All campuses** – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

Clinical Laboratories – **Penn State** **Health only** – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes but are no longer needed for clinical use. Upload a copy of “HRP-901 - Human Body Fluids for Research Form” in CATS IRB.

Clinical Research Center (CRC) Advisory Committee – **All campuses** – Research involves the use of CRC services in any way.

Conflict of Interest Review – **All campuses** – Research has one or more of study team members indicated as having a financial interest.

Radiation Safety – **Penn State** **Health only** – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of “HRP-903 - Radiation Review Form” in CATS IRB.

IND/IDE Audit – **All campuses** – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

Scientific Review – **Penn State Health only** – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Health Cancer Institute (PSCI) Protocol Review Committee or the PSCI Disease Team is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website.

# Multi-Site Study

## If this is a multi-site study (i.e., a study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol) and the Penn State PI is the lead investigator, describe the processes to ensure communication among sites in the sections below.

[Do not type here]

## Other sites

List the name and location of all other participating sites. Provide the name, qualifications and contact information for the principal investigator at each site and indicate which IRB will be reviewing the study at each site.

## 

Not applicable.

## Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site’s IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

Not applicable.

## Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

Not applicable.

## Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

Not applicable.

## Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

Not applicable.

## Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

Not applicable.

# Adverse Event Reporting

## Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

*In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.*

# Study Monitoring, Auditing and Inspecting

## Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

*The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).*

# Future Undetermined Research: Data and Specimen Banking

If this study is collecting **identifiable** data and/or specimens that will be banked for future **undetermined** **research**, please describe this process in the sections below. This information should not conflict with information provided in section 22 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly). If **NOT applicable**, indicate as such below in all sections.

[Do not type here]

## Data and/or specimens being stored

## Identify what data and/or specimens will be stored and the data associated with each specimen.

Not applicable.

## Location of storage

Identify the location where the data and/or specimens will be stored.

Not applicable.

## Duration of storage

Identify how long the data and/or specimens will be stored. If data and/or specimens will be stored indefinitely, indicate as such.

Not applicable.

## Access to data and/or specimens

Identify who will have access to the data and/or specimens.

## 

Not applicable.

## Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

Not applicable.

## Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

The PI will not have information about who accesses shared data unless the data are cited, and will not otherwise monitor data use or re-use or inform participants.

# References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

Abramov, I., Gordon, J., Feldman, O., & Chavarga, A. (2012). Sex & vision I: Spatio-temporal resolution. *Biology of Sex Differences*, *3*(1), 20.

Ekstrom, R.B., French, J.W., Harman, H.H., (1976). Kit of Factor-referenced Cognitive Tests. *Educational Testing Service*, Princeton, NJ.

Lippa, R. (1991). Some psychometric characteristics of gender diagnosticity measures: Reliability, validity, consistency across domains, and relationship to the big five. *Journal of Personality and Social Psychology*,61(6), 1000-1011.

Murray, S. O., Schallmo, M. P., Kolodny, T., Millin, R., Kale, A., Thomas, P., ... & Tadin, D. (2018). Sex differences in visual motion processing. *Current biology*, *28*(17), 2794-2799.

Vandenberg, S. G., & Kuse, A. R. (1978). Mental rotations, a group test of three-dimensional spatial visualization. *Perceptual and Motor Skills*, 47, 599-604.

# Confidentiality, Privacy and Data Management

**IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete “HRP-598 Research Data Plan Review Form.” In order to avoid redundancy, for this section state “See the Research Data Plan Review Form” if you are conducting Penn State Health research. Delete all other sub-sections of section 22.**

**For research being conducted at Penn State Health or by Penn State Health researchers only: The research data security and integrity plan is submitted using “HRP-598 – Research Data Plan Review Form.”**

**Refer to Penn State College of Medicine IRB’s “Standard Operating Procedure Addendum: Security and Integrity of Human Research Data,” which is available on the IRB’s website. In order to avoid redundancy, for this section state “See the Research Data Plan Review Form” if you are conducting Penn State Health research. Delete all sub-sections of section 22.**

**For all other research**: complete the following section. Please refer to [PSU Policy AD95](https://policy.psu.edu/policies/ad95#C) for information regarding information classification and security standards and requirements. It is recommended that you work with local IT staff when planning to store, process, or access data electronically to ensure that your plan can be carried out locally and meets applicable requirements. If you have questions about Penn State’s Policy AD95 or standards or need a consultation regarding data security, please contact [security@psu.edu](mailto:security@psu.edu).

## Which of the following identifiers will be recorded for the research project? Check all that apply. If none of the following identifiers will be recorded, do not check any of the boxes.

|  |  |  |
| --- | --- | --- |
|  | Hard Copy Data | Electronic  Stored  Data |
| Names and/or initials (including on signed consent documents) |  |  |
| All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, |  |  |
| All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older |  |  |
| Telephone numbers |  |  |
| Fax numbers |  |  |
| Electronic mail addresses |  |  |
| Social security numbers |  |  |
| Medical record numbers |  |  |
| Health plan beneficiary numbers |  |  |
| Account numbers |  |  |
| Certificate/license numbers |  |  |
| Vehicle identifiers and serial numbers, including license plate numbers |  |  |
| Device identifiers and serial numbers |  |  |
| Web Universal Resource Locators (URLs) |  |  |
| Internet Protocol (IP) address numbers |  |  |
| Biometric identifiers, including finger and voice prints |  |  |
| Full face photographic images and any comparable images |  |  |
| Any other unique identifying number, characteristic, or code (such as the pathology number) |  |  |
| Study code number with linking list |  |  |
| Genomic sequence data |  |  |
| State ID numbers |  |  |
| Passport numbers |  |  |
| Driver’s license numbers |  |  |

## If storing paper records of research data, answer the following questions:

### Where will the paper records, including copies of signed consent forms, associated with this research study will be stored?

Any paper documents are filed in a locked filing cabinet that is located in locked 503 Moore.

### How will the paper records be secured?

The paper records will be recorded in a locked filing cabinet in a locked room.

### How will access to the paper records be restricted to authorized project personnel?

Only research staff under the supervision of Dr. Rick Gilmore have access to 503 Moore and have the key to open the locked filing cabinet which stores the paper records of this study.

## If storing electronic records of research data, indicate where the electronic data associated with this research study will be stored. Check all that apply.

Penn State-provided database application. Check which of the following database applications are being used (check all that apply):

Penn State REDCap

Other – Specify - provided and approved database application:

Penn State, College, or Department IT file server

Box.psu.edu (Apply for a Box NPA here: https://box.psu.edu/non-person-account/)

Web-based system provided by the sponsor or cooperative group - Specify URL and contact information:

Other – Specify the database application or server:

Provide details about the data security features or attach security documentation provided by sponsor or group:

If there is a list/key that links indirect identifiers (code numbers, participant IDs, etc.) to direct identifiers, that list must not be comingled (i.e., stored in the same location) as the identifiable data, including copies of signed informed consent forms. Additionally, access to that list/key must be restricted to authorized project personnel.

## Is there a list/key that links code numbers to identifiers?

Yes - explain how the list that links the code to identifiers is stored separately from coded data:

Not applicable, there is no list that links code numbers to identifiers. Skip to section 22.6.

## Is there a list of people who have access to the list/key?

Yes – explain how access to that list is restricted and why certain persons require access.

No – explain why not:

## Describe the mechanism in place to ensure only approved research personnel have access to the stored research data (electronic and paper).

Password-protected files

Role-based security

Specify all other mechanisms used to ensure only permitted users have access to the stored research data.

**Only authorized research assistants have access to 503 Moore. All data are either stored in a locked file cabinet in a locked office or stored on password/access protected file servers.**

The use of mobile devices or wireless activity trackers to collect identifiable research data must be approved by the Office of Information Security. Before completing this section, please contact [security@psu.edu](mailto:security@psu.edu) to confirm approval.

## Will any research data (such as survey data) be collected on a mobile device, such as an electronic tablet, cell phone, or wireless activity tracker?

No

Yes - answer the following questions:

### Specify the provider of the mobile devices(s)

Supplied by the sponsor

Penn State owned device

A personal device

Other – Please specify source:

* + - 1. Specify the type(s) of mobile device(s) that will be used to capture data and all identifiers captured on the mobile device(s). Please list all devices, and if more than one, the identifiers to be collected on each.

### Specify the type of data collected on the mobile devices(s).

### Specify the application or website used to collect the data from the mobile device, if applicable.

**Penn State Qualtrics (de-identified data only)**

* + - 1. Describe the measures taken to protect the confidentiality of the data collected on mobile device(s). Please address physical security of the device(s), electronic security, and secure transfer of data from device(s) to the previously indicated data/file storage location provided in section 22.3.

* 1. Specify the

The use of online survey tools and email to collect or send research data containing identifiers that represent more than minimal risk to subjects must be approved by the Office of Information Security. Before completing this section, please contact security@psu.edu.

## Will any research data be directly entered/sent by subjects over the internet or via email (e.g., data capture using on-line surveys/questionnaires, surveys via email, observation of chat rooms or blogs)?

No

Yes - answer the following questions:

### Specify the identifiers collected over the internet or via email (Including IP addresses if IP addresses will be collected).

**Penn State Qualtrics (https://pennstate.ca1.qualtrics.com) will be administered.**

### Specify the type of data collected over the internet or via email.

**Surveys about the basic demographic information (gender, major, year in the school, etc.), hobbies, spatial ability and spatial ability will be collected via Penn State Qualtrics.**

### Describe the measures taken to protect the confidentiality of the data collected?

**Only the random study code number assigned to that participant will be listed in data of the surveys and behavioral test. We will not have a list/key that links code numbers to identifiers.**

### Describe how the research team will access the data once data collection is complete.

**The research team will access the data in one folder in Box.psu.edu where the data was stored.**

### If the research involves online surveys, list the name(s) of the service provider(s) that will be used for the survey(s) (e.g., REDCap, Penn State licensed Qualtrics, Survey Monkey, Zoomerang)? (Note: The IRB strongly recommends the use of REDCap for online surveys that obtain sensitive identifiable human subjects data.)

Penn State REDCap

Penn State Qualtrics (de-identified data only)

Other - Please specify:

Application:

URL (If applicable):      

### If the answer above is “Other” contact [security@psu.edu](mailto:security@psu.edu) for approval of an alternative data capture method

Depending on the nature of the subject matter involved, certain security requirements must be in place for the audio and/or video recording or photographing of subjects. If the subject matter presents more than minimal risk to the subjects, then, before completing the section below, please contact the Office of Information Security at [security@psu.edu](mailto:security@psu.edu) to confirm whether these requirements are required.

* 1. Specify the

## Will any type of recordings (e.g., audio or video) or photographs of the subjects be made during this study?

No - skip to section 22.10

Yes - answer the following questions:

### What will be used to capture the audio/video/images? Give a brief description of content.

Audio – Describe the intended content of the audio recording:

Video – Describe the intended content of the video recording:

Photographs of the subjects – Describe the intended content of the photographs:

3-D Images – Describe the intended content of the of 3-D images:

Other - Specify:

### How will the recordings/photographs/images be stored (electronically or physically)?

### Where will the recordings/photographs/images be stored?

### Who will have access to the recordings/photographs/images?

### Will any of the recordings be transcribed?

Not applicable

No

Yes – indicate who will be doing the transcribing?

### Will the recordings/photographs be used for purposes other than this research study?

No

Yes - specify purpose(s) (e.g., publication, presentations, educational training, future

undetermined research):

* 1. What type of r

## Certificate of Confidentiality (COC) - Is the research biomedical, behavioral, clinical or other research that is funded by the National Institutes of Health (NIH)?

Yes - check one of the following:

The research involves human subjects as defined by the DHHS regulations (See Worksheet

HRP-310).

The research involves collecting or using biospecimens that are identifiable to an individual.

If collecting or using biospecimens as part of the research, there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.

The research involves the generation of individual level, human genomic data.

**Note: If any of the 4 items above are checked, a COC is automatically issued by NIH and applies to the research. Information about the COC must be included in the consent form.**

No - answer the following question.

If the research is not funded by NIH, will the investigator apply for a COC for this research study?

No

Yes

**Note: For research not funded by NIH, the IRB may require a COC if the research is collecting personally identifiable information and the information is sensitive and/or the research is collecting information that if disclosed could significantly harm or damage the subject.**

## What steps will be taken to protect subjects’ privacy interests? (Check all that apply.)

Identification and recruitment of potential subjects follows procedures consistent with privacy standards

Consent discussion and research interventions will take place in a private setting

Limiting the information being collected to only the minimum amount of data necessary to accomplish the research purposes

Limiting the people with access to the identifiable research data to the minimum necessary as specified in the application and consent process

Other – Specify:

## What is the process for ensuring correctness of data entry?

Double data entry to reduce risk of errors

Electronic edit checks to ensure data being entered are not obviously incorrect

Random internal quality and assurance checking of research data

Direct entry by subjects

Other - Specify:

## Does this research involve the generation of large-scale human genomic data as defined in NIH Genomic Data Sharing Policy (<http://gds.nih.gov>)?

No

Yes – If Yes, describe the plan for de-identifying the dataset before sharing it with NIH-designated data repositories.

## The European Union (EU) General Data Protection Regulation (GDPR)

### To determine if the research is subject to the GDPR answer the following questions:

#### Will the Penn State principal investigator, or another entity under the Penn State principal investigator’s direction, be collecting, recording, storing, using, any personal data\* of any subjects physically located in the European Economic Area (EEA)\*\* at the time of data collection (even if the subject is NOT an EEA resident) or any EEA citizens? (This includes recruitment through social media sites, use of third party internet sites, mobile devices or apps to collect data, and/or direct receipt of data from subjects.)

No

Yes (This research may be subject to the GDPR)

#### Does this research involve the transfer of personal data collected under the GDPR from an EEA country? (This includes direct transfer of data from research collaborators.)

No

Yes (This research may be subject to the GDPR)

### If the research may be subject to the GDPR as indicated in the answers to the questions above, answer the following:

#### Will any of the data fall into one of the following categories: health data, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data used for purpose of identifying an individual, sex life or sexual orientation?

No

Yes

#### Will any of the data be related to criminal convictions or offenses?

No

Yes

**Comments on any of the above responses:**

\* “Personal data” means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

\*\* European Economic Area (EEA) – Includes the 28-member states of the European Union (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia Spain, Sweden, UK) and Norway, Iceland, Lichtenstein.

## Does this research involve transfer or disclosure of data and/or specimens to and/or from Penn State?

No - skip the remainder of section 22.15.

Yes - answer the following questions.

Check all that apply:

**Data** are being transferred or disclosed **to** Penn State

What is the name of the third party(ies) (the institution, sponsor, etc.) sending or providing the data?

Is the third party requiring us to sign a contract regarding the data?

Yes - If Yes, this contract must go through the Office of Sponsored Programs [**https://www.research.psu.edu/osp/overview-pages/data-use-agreements**](https://www.research.psu.edu/osp/overview-pages/data-use-agreements)

No

**Data** are being transferred or disclosed **from** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving or accessing the data?

**Note: Data transfers or disclosures may require a Data Use Agreement (DUA).**

**Specimens** are being transferred **to** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) sending the specimens?

**Specimens** are being transferred **from** Penn State

What is the name(s) of the third party(ies) (the institution, sponsor, etc.) receiving the specimens?

**Note: All material transfers, either sending or receiving, require a Material Transfer Agreement (MTA).  Please contact the Office of Technology Management for more information.**

### Describe how the data/specimens will be securely transferred or disclosed to/from the third party(ies).

### How are the research data/specimens being transferred from and/or sent to the third party(ies)? Complete the appropriate section(s) and check all that apply within each completed section.

#### Data being transferred or disclosed to Penn State:

Data are being received in aggregate/metrics (just counts, no individual data)

De-identified individual data are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

Coded research data without any identifiers are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being received and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being received and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list

Data with identifiers along with the linking list are being received

Other – Specify:

#### Data being transferred or disclosed from Penn State:

Data are being sent in aggregate/metrics (just counts, no individual data)

De-identified individual data are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

Coded research data without any identifiers are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

Coded research data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being sent and the linking list remains with the entity sending the data; the recipient of the data will not have access to the linking list

Data with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being sent and the linking list remains with the entity sending the data; the recipient of the data will have access to the linking list

Data with identifiers along with the linking list are being sent

Other – Specify:

#### Specimens being transferred or disclosed to Penn State:

De-identified specimens are being received and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

Coded specimens without any identifiers are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being received and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list

Coded specimens with identifiers along with the linking list are being received

Other – Specify:

#### Specimens being transferred or disclosed from Penn State:

De-identified specimens are being sent and there is no linking list at either institution (no identifiers, or links to identifiers, such as code numbers)

Coded specimens without any identifiers are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3 aside from Study Code) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will not have access to the linking list

Coded specimens with identifiers (such as dates and/or any of the identifiers listed in section 22.15.3) are being sent and the linking list remains with the entity sending the specimens; the recipient of the specimens will have access to the linking list

Coded specimens with identifiers along with the linking list are being sent

Other – Specify:

### If transferring data/specimens with identifiers to or from Penn State, which of the following identifiers will be included with the data/specimens? Check all that apply:

|  |  |
| --- | --- |
| Names | Medical record numbers |
| Initials | Health plan beneficiary numbers |
| Street address | Account numbers |
| City | Certificate/license numbers |
| Driver’s License numbers | Passport numbers |
| State | State ID numbers |
| Zip Codes | Vehicle identifiers and serial numbers, including license plate numbers |
| County | Device identifiers and serial numbers |
| Geocodes | Web Universal Resource Locators (URLs) |
| Precincts | Internet Protocol (IP) address numbers |
| All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death | Biometric identifiers, including finger and voice prints |
| Ages > 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older | Full face photographic images and any comparable images |
| Telephone numbers | Any other unique identifying number, characteristic, or code (such as the pathology number)  Specify: |
| Fax numbers | Study code numbers |
| Electronic mail addresses | Master list linking study code numbers to subject(s) |
| Social security numbers | Genomic sequence data |
|  | Other – specify: |