Task Switching Behavior Between Target Templates During Visual Search in Healthy Adults

Protocol Number*: 6 R15 EY030247-01A1

National Clinical Trial (NCT) Identified Number: NCT05786651

Principal Investigator*: Nancy Carlisle

Sponsor:Lehigh University

Grant Title: Examining Flexibility in Visual Attentional Control

Grant Number*: 1R15EY030247-01A1

Funded by: NEI

Version Number: v.1

10 May 2023

CONFIDENTIALITY STATEMENT

This document is confidential communication. Acceptance of this document constitutes agreement by the recipient that no unpublished information contained herein will be published or disclosed without prior approval of the Principal Investigator or other participating study leadership and as consistent with the NIH terms of award.

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STATEMENT OF COMPLIANCE

(1) [The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812).

National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management, or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is consented. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.]

INVESTIGATOR'S SIGNATURE

The signature below constitutes the approval of this protocol and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines, as described in the *Statement of Compliance* above.

Principal Investigator or Clinical Site Investigator:

Signed: _____ Date: _____

Name*: Nancy Carlisle

Title*: Associate Professor of Psychology and Cognitive Science

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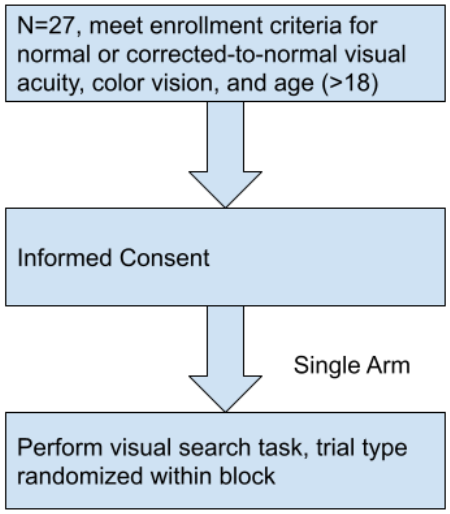
1 PROTOCOL SUMMARY

No text is to be entered in this section; rather it should be included under the relevant subheadings below. It may be useful to complete this section after the relevant sections in the protocol have been completed.

1.1 SYNOPSIS

Title:	Examining Flexibility in Attentional Control
Grant Number:	*1R15EY030247*
Study Description:	*Examine task switching when participants receive a target color cue or distractor color cue, and meaning and/or color change across trials*
Objectives*:	*Examine task switching*
Endpoints*:	*Single day of testing*
Study Population:	*27, 15 F/ 11M, healthy adults, Lehigh University*
Phase* or Stage:	*NA*
Description of Sites/Facilities Enrolling Participants:	*Lehigh University*
Description of Study Intervention/Experimental Manipulation:	*participants receive a target color cue or distractor color cue, and meaning and/or color change across trials*
Study Duration*:	*2 months*
Participant Duration:	*30 minutes*

1.2 SCHEMA


N=27, meet enrollment criteria for normal or corrected-to-normal visual acuity, color vision, and age (>18)
Informed Consent
Single Arm
Perform visual search task, trial type randomized within block

1.3 Schedule of Activities

	Pre-screening (Pre-consent)	Visit 1 Day 1
Participants only see experiment if meet criteria	X	
Informed Consent		X
Demographics		X
Outcome Evaluation		
Visual Search Performance		X
Randomization (Trial order)		X
Adverse Events Reporting		X

2 INTRODUCTION

2.1 Study Rationale

The PI provided the first evidence that attentional control can also be used to ignore known distractor features (Arita, Carlisle, & Woodman, 2012). In this study, participants received a cue before each trial of a visual search task where they searched for a shape-defined target (a gap-up or gap-down Landolt-c) and reported the location of the gap. The cue could be a positive cue (indicating the target would appear in that color in the upcoming array), a negative cue (indicating the target *would not* appear in that color in the upcoming array), or a neutral cue (the cued color did not appear in the upcoming array). These cue meanings were manipulated across blocks. Importantly, because only two colors appeared in the search array, the positive and negative cues had the same information value. If participants used the cue, they could reduce the number of items they needed to search to find the target by half. We found participants can use visual attentional control to actively ignore items based on a feature cue, as indicated by reaction time (RT) benefits for the negative cued condition compared to the neutral condition.

In this study, participants will receive a cue on each trial that indicates a feature (e.g. red) and the cue meaning (positive + or negative -). Across trials, we will be able to independently alter the feature template and the cue meaning (Figure 5A). This will allow us to ensure the results are driven by shifts in the cue meaning, and not simply alterations to the color that is cued. This will lead to trials where both the feature and the meaning repeat (RE-repeat trials), trials where only the cue feature changes (CC-color change, meaning repeat), trials where only the cue meaning changes but the color repeats (MC-meaning change, color repeat), and trials where both feature and cue meaning change (BC-both change). To look for task switching costs, we will subtract the reaction times for repeat trials from each type of switch trials. Importantly, the visual search is defined by a shape-defined target across all trials, meaning that there should be no cross talk or response interference that could interfere with our ability to measure task-switching costs (Koch, Poljac, Müller, & Kiesel, 2018).

2.2 Background

Previous research has shown that, when there are no competing task demands, attention is likely to be directed to items in the visual field that match working memory (Downing, 2000). This suggests that the prepotent response is to attend to memory-matching items, whereas to utilize a negative cue one must actively avoid attending the memory-matching items. This is a good example of how higher-order cognitive control can be used to inhibit prepotent responses. A similar example from oculomotor control is the anti-saccade task. In this task, participants must either make a pro-saccade toward a cue or and anti-saccade away from the cue, depending on the identity of the cue. A unidirectional switch cost has been shown within the anti-saccade task when participants must engage in task switching between pro- and

anti-saccades (Weiler & Heath, 2012). When participants switch from an anti-saccade task to a pro-saccade task, there is a typical switch cost as compared to pro-saccade repetition. However, the opposite pattern is found for anti-saccades- participants are either faster to perform an anti-saccade after a prosaccade (task switch) compared to an anti-saccade repetition (Barton, et. al, 2002) or show no task switch effect (Weiler & Heath, 2012). This is thought to reflect a residual inhibition of the pre-potent response following an anti-saccade. This slows a subsequent pro-saccade, but can also slow an anti-saccade as well. Therefore, the unidirectional switch cost is a hallmark of inhibition within the oculomotor system.

2.3 Risk/Benefit Assessment

The following subsections should include a discussion of known risks and benefits, if any, to human participants. Text from the corresponding sections of the Human Subjects section of the grant application, and/or IRB package may be used here.

2.3.1 Known Potential Risks

The risks associated with the behavioral tasks are similar to working on a computer or playing a video game. They include possible eye strain, and boredom. We will try to reduce the possibility of these risks by providing frequent breaks during the experiment (approximately every 5 minutes during data recording).

2.3.2 Known Potential Benefits

There are no direct benefits expected for the participants, and no clinical benefits, however many participants enjoy being able to learn more about how we use behavioral responses to understand more about cognition.

The cognitive processes subserving attention and memory are critical for daily functioning. Individuals who have deficits in these cognitive processes, such as individuals with Schizophrenia, often have difficulty in succeeding in their pursuits. Learning more about how these processes occur in typical adults may lead to insights into how to help individuals with cognitive deficits, or improve these functions in typical adults.

2.3.3 Assessment of Potential Risks and Benefits

The risks associated with the behavioral tasks are similar to working on a computer or playing a video game, and the benefits for our understanding of basic human cognition are present. Therefore, we think the benefits outweigh the risks.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS	PUTATIVE MECHANISMS OF ACTION
Primary			
Compare Task-Switching Costs for Positive Target Cues and Negative Distractor Cues	*Reaction Time Accuracy*	*Cognitive Function*	*Conflict in Cognitive Control leads to task-switching costs*

4 STUDY DESIGN

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

4.1 Overall Design

Hypothesis: If the negative template requires the general inhibition of the oculomotor system to reduce the likelihood of the prepotent response, we expect to find a unidirectional switch cost. Within-Subjects, single arm design, single site.

Visual Search Information Type (target or distractor information) Participants will have information about targets or distractors via cues before a visual search trials, in different trials of the intervention.

4.2 Scientific Rationale for Study Design

Within-subjects design lead to strong conclusions about cognitive function.

4.3 Justification for Intervention

Typical duration of trials, 481, for behavioral studies.

4.4 End-of-Study Definition

Complete 481 trials in single day.

5 STUDY POPULATION

5.1 Inclusion Criteria

In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form
2. Normal or corrected-to-normal visual acuity
3. Normal color vision
4. >=18 years of age

5.2 Exclusion Criteria

5.3 Lifestyle Considerations

N/A

5.4 Screen Failures

N/A

5.5 Strategies for Recruitment and Retention

We plan to include women and minorities in this study. Participants will be recruited from the Lehigh University community. As such, we expect the ethnicity distribution of our sample to roughly match the ethnicity distribution of Lehigh (see Figure 1). Lehigh's student body is 55% male and 45% female, so we also expect this to be represented in our sample. We will gather information on participant age, sex, and ethnicity for reporting purposes, and these factors will be entered into analysis as covariates in our statistical analyses. We have no a priori expectations of differences based on these factors from prior research, but will include these factors in our analysis to ensure that previous research has not neglected between group differences.

Rationale for selection: Our research is designed to assess basic research related to human visual attentional control. As such, we assume the basic processes will be shared among most adults humans. We will take a convenience sample of adults to learn more about these basic procedures.

Outreach programs: Participants will be recruited from low-level Psychology participant pools, which are often taken as a general education requirement at Lehigh. Paid participants will be recruited via fliers and the Lehigh Paid Participant Pool. Fliers are posted around Lehigh's campus as well as in public locations within the community (grocery stores, other higher education institutions, coffee shops, etc.). Most paid participants come from the Lehigh community, so we expect the sampling to draw heavily from Lehigh.

6 STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

6.1 Study Intervention(s) or Experimental Manipulation(s) Administration

6.1.1 Study Intervention or Experimental Manipulation Description

Participants will receive one of three types of visual cues before performing a visual search task. Positive cues for visual search (cues to enhance), or negative cues for visual search (cues to suppress). After subjects receive the color cue for a trial, they will perform a visual search task for a shape-defined target (landolt-C). We will examine task switching costs for changes in the color of the cue, changes in the meaning of the cue, neither or both. We will measure 'task-switching costs' by contrasting reaction times when an aspect of the trial changes compared to when neither aspect of the trial changes compared to the previous trials. We will collect behavioral results using Matlab and a computer.

6.1.2 Administration and/or Dosing

Single day of testing, all conditions occur within single block of testing behavior.

6.2 Fidelity

6.2.1 Interventionist Training and Tracking

Participants are all read the same instructions before trials begin to ensure understanding.

6.3 Measures to Minimize Bias: Randomization and Blinding

Within-subjects manipulation, no blinding.

6.4 Study Intervention/Experimental Manipulation Adherence

Practice trials were administered to ensure participants understood the task instructions.

6.5 Concomitant Therapy

N/A

6.5.1 Rescue Therapy

N/A

7 STUDY INTERVENTION/EXPERIMENTAL MANIPULATION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 Discontinuation of Study Intervention/Experimental Manipulation

Participants are informed their participation in voluntary, and they may stop participating at any time during the 30-minute testing session.

7.2 Participant Discontinuation/Withdrawal from the Study

N/A

7.3 Lost to Follow-Up

N/A

8 STUDY ASSESSMENTS AND PROCEDURES

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

8.1 Endpoint and Other Non-Safety Assessments

Participants receive task instructions, practice the task, and are allowed to ask questions prior to beginning the experimental block.

8.2 Safety Assessments

Researchers monitor for any safety concerns (e.g. headaches), and participants are informed they may withdraw from the study at any time as part of our consent process.

8.3 Adverse Events and Serious Adverse Events

8.3.1 Definition of Adverse Events

This protocol uses the definition of adverse event from 21 CFR 312.32 (a): any untoward medical occurrence associated with the use of an intervention in humans, ***whether or not considered intervention-related***.

8.3.2 Definition of Serious Adverse Events

Adverse events which go beyond typical daily occurrences.

8.3.3 Classification of an Adverse Event

1.1.1.1 Severity of Event

All AEs will be assessed by the principal investigator. Any adverse events that go beyond typical events in daily life from computer use (e.g. headache) will be reported to Lehigh IRB.

1.1.1.2 Relationship to Study INTERVENTION/Experimental Manipulation

Consultation with the Lehigh IRB will determine if the AEs are related or unrelated to the basic science intervention.

1.1.1.3 Expectedness

We expected events such as mild headache or boredom within our design, as these are typical for computer-based tasks. We did not expect any more serious adverse events. All researchers are told to report any potential adverse events to the PI.

1.1.2 Time Period and Frequency for Event Assessment and Follow-Up

Day of testing. If the PI has any concerns about an adverse event, she may directly reach out to the participant to obtain additional details or check on the participant.

1.1.3 Adverse Event Reporting

Adverse events are reported to Lehigh's IRB.

1.1.4 Serious Adverse Event Reporting

The PI will be responsible for conducting an evaluation of a serious adverse event and shall report the results of such evaluation to the NIH and the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working days after the investigator first learns of the event.

1.1.5 Reporting Events to Participants

N/A

1.1.6 Events of Special Interest

N/A

1.1.7 Reporting of Pregnancy

N/A

1.2 Unanticipated Problems

1.2.1 Definition of Unanticipated Problems

- *We experience unanticipated computer issues (e.g. code not working, file not saving) occasionally.*

1.2.2 Unanticipated Problems Reporting

The PI will report unanticipated problems (UPs) that are deemed significant (e.g. not the expected unanticipated issues listed above) to the reviewing Institutional Review Board (IRB). The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number
- A detailed description of the event, incident, experience, or outcome
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP

*See **CD Section 8.4.1** for additional example text applicable for devices.*

1.2.3 Reporting Unanticipated Problems to Participants

N/A

2 STATISTICAL CONSIDERATIONS

2.1 Statistical Hypotheses

If the negative template requires the general inhibition of the oculomotor system to reduce the likelihood of the prepotent response, we expect to find a unidirectional switch cost (e.g. a switch cost for positive cues which is not present for negative cues).

2.2 Sample Size Determination

GPower analysis: Repeated measures ANOVA with 8 factors (4 different trial types x 2 cue types, positive vs. negative cues)

F tests - ANOVA: Repeated measures, within factors

Analysis:	A priori: Compute required sample size			
Input:	Effect size f	=	0.2	
	α err prob	=	0.05	
	Power (1-β err prob)	=	0.8	
	Number of groups	=	1	
	Number of measurements	=	8	
	Corr among rep measures	=	0.5	
	Nonsphericity correction ε	=	1	
Output:	Noncentrality parameter λ	=	15.3600000	
	Critical F	=	2.0668747	
	Numerator df	=	7.0000000	
	Denominator df	=	161	
	Total sample size	=	24	
	Actual power	=	0.8115711	

We will recruit 24 participants to meet the required sample size.

2.3 Populations for Analyses

Participants will be included if they complete the experimental session, have saved data, and do not fall below 2.5 s.d. below the mean of accuracy performance for the group.

2.4 Statistical Analyses

2.4.1 General Approach

As a guide, the following should be addressed, as appropriate:

- *Descriptive statistics:means with standard deviations.*
- *Inferential tests: p-value=.05*

2.4.2 Analysis of the Primary Endpoint(s)

For both Reaction time and Accuracy, we will perform an ANOVA with these factors: Cue Meaning (Target Color Positive Cue or Distractor Color Negative Cue) x Cue Meaning Repetition (Repeat, Non-Repeat) X Cue Color Repetition (Repeat, Non-Repeat) Repetition.

2.4.3 Safety Analyses

N/A

2.4.4 Baseline Descriptive Statistics

N/A

2.4.5 Planned Interim Analyses

N/A

2.4.6 Sub-Group Analyses

We will include sex as a between-subjects variable in our analysis.

2.4.7 Tabulation of Individual Participant Data

N/A

2.4.8 Exploratory Analyses

N/A

3 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

3.1 Regulatory, Ethical, and Study Oversight Considerations

3.1.1 Informed Consent Process

Informed consent will occur before the study session begins.

3.1.1.1 Consent/assent and Other Informational Documents Provided to participants

Consent forms describing in detail the study intervention, study procedures, and risks will be given to the participant and written documentation of informed consent will be completed prior to starting the study intervention.

Behavioral Research on Human Cognition: Lehigh IRB 864576-10

3.1.1.2 Consent Procedures and Documentation

Participants are told: Ok, the next thing I will have you do is fill out the informed consent document. The important things to note about the consent document are that:
>Your participation is voluntary
>If you choose to withdraw your participation, you will still be given your experimental credit
>Your name will not be associated with your data
>Your name will be kept confidential

3.1.2 Study Discontinuation and Closure

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to NEI. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform the Institutional Review Board (IRB), and sponsor/funding agency and will provide the reason(s) for the termination or suspension.

3.1.3 Confidentiality and Privacy

We will collect behavioral results using Matlab and a computer. All data will be recorded using a non-identifiable participant code (e.g. TS_B01) to ensure participant confidentiality. All informed consent documents will be kept in a lockable cabinet in a locked room.

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and funding agency. This confidentiality is extended to the data being collected as part of this study. Data that could be used to identify a specific study participant will be held in strict confidence within the research team. No personally-identifiable information from the study will be released to any unauthorized third party without prior written approval of the sponsor/funding agency.

All research activities will be conducted in as private a setting as possible.

The study monitor, other authorized representatives of the sponsor or funding agency, representatives of the Institutional Review Board (IRB), regulatory agencies or representatives from companies or organizations supplying the product, may inspect all documents and records required to be maintained by the investigator.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor/funding agency requirements.

At the end of the study, all study databases will be archived at Open Science Framework.

Measures Taken to Ensure Confidentiality of Data Shared per the NIH Data Sharing Policies
It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see *https://grants.nih.gov/policy/sharing.htm*). The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse (e.g., all data will be thoroughly de-identified and will not be traceable to a specific study participant). Plans for archiving and long-term preservation of the data will be implemented, as appropriate.

Certificate of Confidentiality
To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (see *https://humansubjects.nih.gov/coc/index*). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

3.1.4 Future Use of Stored Specimens and Data

Data collected for this study will be analyzed and stored at Lehigh University. After the study is completed, the de-identified, archived data will be transmitted to and stored on the Open Science

Framework, for use by other researchers including those outside of the study. Reuse of anonymized data will be outlined in the informed consent.

3.1.5 Key Roles and Study Governance

Principal Investigator
Nancy Carlisle, PhD, Associate Professor of Psychology and Cognitive Science
Lehigh University
17 Memorial Drive, Bethlehem, PA, 18017
610-758-5122
nbc415@lehigh.edu

3.1.6 Safety Oversight

Safety oversight will be maintained by the PI, in consultation with the researchers, and, if necessary, Lehigh's IRB.

3.1.7 Clinical Monitoring

The PI and senior personnel (e.g. Post-doc, graduate students) will be responsible for training researchers and ensuring adherence to research protocols.

3.1.8 Quality Assurance and Quality Control

Quality control (QC) procedures will be implemented as follows:

Informed consent --- Study staff will review the consenting process and consent documents. Feedback will be provided to the study team to ensure proper consenting procedures are followed.

Source documents and the electronic data --- Data will be initially captured on research computers (see **Section 10.1.9, Data Handling and Record Keeping**) and the anonymized data will ultimately be maintained on a secure Lehigh data storage system.

Intervention Fidelity — Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study by providing scripts for our research personnel. see **Section 6.2.1, Interventionist Training and Tracking**.

Protocol Deviations – The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

3.1.9 Data Handling and Record Keeping

No text is to be entered in this section; rather it should be included under the relevant subheadings below.

Each participating site will maintain appropriate medical and research records for this trial, in compliance with ICH GCP and regulatory and institutional requirements for the protection of confidentiality of participants. As part of participating in a NIH-sponsored or NIH-affiliated study, each site will permit authorized representatives of the NIH, sponsor, and regulatory agencies to examine (and when permitted by applicable law, to copy) clinical records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress, and data validity. Indicate who will have access to records.

The following subsections should include a description of the data handling and record keeping for the conduct of the trial.

3.1.9.1 Data Collection and Management Responsibilities

We will collect behavioral results using Matlab and a computer. All data will be recorded using a non-identifiable participant code (e.g. TS_B01) to ensure participant confidentiality. All informed consent documents will be kept in a lockable cabinet in a locked room.

Data collection will be the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

3.1.9.2 Study Records Retention

Study documents will be retained for a minimum of 5 years have elapsed since the end of the study.

3.1.10 Protocol Deviations

This protocol defines a protocol deviation as any noncompliance with the clinical trial protocol, International Council on Harmonisation Good Clinical Practice (ICH GCP). The noncompliance may be either on the part of the investigator, or the study site staff. As a result of deviations, corrective actions will be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- Section 4.5 Compliance with Protocol, subsections 4.5.1, 4.5.2, and 4.5.3
- Section 5.1 Quality Assurance and Quality Control, subsection 5.1.1
- Section 5.20 Noncompliance, subsections 5.20.1, and 5.20.2.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations from protocol. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements.

3.1.11 Publication and Data Sharing Policy

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers after the completion of the primary endpoint and publishing of the study by contacting the PI or checking on OSF. Considerations for ensuring confidentiality of these shared data are described in Section 10.1.3.

3.1.12 Conflict of Interest Policy

The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial. The study leadership in conjunction with the NEI has established policies and procedures for all study group members to

disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

3.2 Additional Considerations

3.3 Abbreviations and Special Terms

The list below includes abbreviations utilized in this template. However, this list should be customized for each protocol (i.e., abbreviations not used should be removed and new abbreviations used should be added to this list). Special terms are those terms used in a specific way in the protocol. For instance, if the protocol has therapist-participants and patient-participants, those terms could be included here for purposes of consistency and specificity.

AE	Adverse Event
ANOVA	Analysis of Variance
CFR	Code of Federal Regulations
EC	Ethics Committee
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FFR	Federal Financial Report
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
NCT	National Clinical Trial
NEI	National Eye Institute of NIH
NIH	National Institutes of Health
NIH IC	NIH Institute or Center
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

3.4 Protocol Amendment History

*The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A **Summary of Changes** table for the current amendment is located in the **Protocol Title Page**.*

Version	Date	Description of Change	Brief Rationale

4 REFERENCES

Arita, J. T., Carlisle, N. B., & Woodman, G. F. (2012). Templates for rejection: configuring attention to ignore task-irrelevant features. Journal of experimental psychology: human perception and performance, 38(3), 580.

Barton, J. J., Cherkasova, M. V., Lindgren, K., Goff, D. C., Intriligator, J. M., & Manoach, D. S. (2002). Antisaccades and task switching: studies of control processes in saccadic function in normal subjects and schizophrenic patients. Annals of the New York Academy of Sciences, 956(1), 250-263.

Downing, P. E. (2000). Interactions between visual working memory and selective attention. Psychological science, 11(6), 467-473.

Weiler, J., & Heath, M. (2012). The prior-antisaccade effect: Decoupling stimulus and response inhibits the planning and control of subsequent prosaccades. Journal of Vision, 12(9), 1253-1253.