

Day of Visit Protocol

Necessary Materials:

- Tissues
- Hand sanitizer
- Sanitizing wipes
- Lubricant eye drops
- Small, latex-free gloves
- CO2 canisters

Before Visit:

1. Bring a physical ClinCard envelope just in case
2. Bring Ishihara Plates
3. Print IRB stamped consent form
 - a. Dropbox/Team Documents/IRBForms/Trigeminal sensitivity in migraine (852532)/2023/Modification June/Aguirre_ICF.pdf
4. Ensure room is stocked with all Necessary Materials
5. Unplug laptop
6. Open a Chrome Tab with lab sas gmail, in case subject emails
7. Open a Chrome Tab with myNoise website (bookmarked)
 - a. <https://mynoise.net/NoiseMachines/whiteNoiseGenerator.php>
 - b. Under “Presets,” click on “Brown”
8. Open a Chrome Tab with ClinCard website (bookmarked)
 - a. <https://www.clincard.com/login/>
 - b. If you are a new user, watch the ClinCard Training Video:
<https://drive.google.com/file/d/1Mdl5mRlfJnNCffsQdnJGT73CgLRd9vdV/view>
 - c. If you want more information, read the Virtual ClinCard Overview:
<https://benhelps.upenn.edu/support/solutions/articles/15000067125-visa-virtual-clincard-training-video> (click on
“Greenphire_ClinCard_Visa_Virtual_Card_Overview_for Coordinators.pdf”)
9. Open the vision_test.pdf for ease of doing the vision screening
 - a. Dropbox/Your_Name/BLNK_admin/Experimental design/Summer 2023/Vision Screening SOPs/vision_test.pdf
10. Open the Variable Pressure Scans Template.pdf
 - a. Dropbox/Your_Name/BLNK_admin/Experimental design/Summer 2023/Variable Pressure Scans Template.pdf
 - b. Type the Subject ID and save as Variable Pressure Scans.pdf in new path
 - i. Dropbox/Your_Name/BLNK_data/expt01_summer2023/SubjectID/YYYY-MM-DD/
 - ii. Keep this open
11. Set up EyeStat device
 - a. EyeStat device should be mounted on tripod
 - b. Black plate with digital meter and variable regular should be stable on the corner of the table, connected to EyeStat device via a blue hose
 - c. Plug power cable into outlet and EyeStat device (ensure light turns on)

- d. Connect external hard drive and keyboard to USB port on EyeStat device
- e. Turn keyboard switch on
- f. Replace canister of CO2
 - i. Unscrew old canister from the variable regulator by turning left
 - ii. Screw new canister in by turning right
- 12. Turn on EyeStat device by holding down the power button
 - a. Log into device: Blink | BlinkTBI1
 - b. If screen locks out, log back in with: 1111
 - c. Run blink software
 - i. Desktop/BlinkTbiMainApp/BlinkTbiMainApp.exe
 - ii. Sign in: blinktbirosters+46@gmail.com | upenn2022!
 - iii. Under “Research” thumbnail, click on “view”
 - iv. Click on the magnifying glass
 - 1. Type subject’s Scan ID
 - a. If subject is new, type the lowest unused Scan ID number
 - d. Add Scan ID to subject’s Variable Pressure Scans.pdf
- 13. Turn off the room lights and turn on the intensity-controlled lamp at the marked level
- 14. Use the restroom

Subject Activity:

- 1. Sanitize hands
- 2. Note the time on subject’s Variable Pressure Scans.pdf

Welcome and thank you very much for participating! Before we begin, let’s go through a quick overview of what today’s experience is going to look like. Feel free to stop me at any point if you have questions. We’ll be spending our time in this room and we’ll start by looking through the consent form. I’ll then have some additional forms and screening information to collect from you. At some point after, I’ll specifically invite you to visit the restroom before we begin the main part of the study. Once all that’s done, we’ll start collecting blink response data, which is the main part of the study. We’ll spend most of the study with you interacting with this device that you see here on the tripod: you’ll look into one end of it, it’ll puff air into your eyes, and we’ll video record the movement of your eyelids, in other words your blink response to those air puffs. I’ll further describe what that experience will look like, but first let’s start with the forms. This consent form should have been emailed to you in advance so perhaps you’ve had a chance to read it over, but if not take your time and look through it. If you have any questions about the contents of it, I’ll do my best to try and answer them for you. If you have no questions, then I’ll ask you to sign on the last page and I’ll sign it as well.

****Hand over consent form****

- 3. Sign the printed IRB stamped consent form
- 4. In-person screening (check appearance of eyelids)
 - a. Checklist:
 - i. Are the palpebral fissures of approximately equal height?

- ii. Do both eyes close completely and equally?
 - iii. Do both eyes open completely and equally?
 - b. *I'll now look at your eyes and check that your eyelids move fully.*
Gently close your eyes.
Now gently open your eyes.
 - c. If subject is ineligible, skip to Protected Subject Info step and ClinCard step and pay an hour's worth
5. Vision screening Google Form
- a. BLNK Vision Screening: <https://forms.gle/LXUTcdiziujhNw5v5>
 - b. Screen normal **corrected** visual acuity (Snellen Chart)
 - i. Ensure overhead lights are on
 - ii. *You will stand on the black line, which is 20 feet away from the Snellen chart, for measurement of your visual acuity. You will wear any corrective glasses you regularly use for your vision and will cover one eye with your hand while facing and viewing the chart with the other eye. You will read starting from the top of the chart line by line until you reach a line where you can no longer distinguish the letters. You will then repeat this process with the other eye.* If they make 1-2 mistakes on a single line, ask them to reread the previous line. If they make 1-2 mistakes on any single line more than once, ask them to stop reading. Record that eye as having the visual acuity of the last line they were able to read without any errors. If they make more than 2 mistakes on any line, ask them to stop reading.
 - iii. Fill in Google Form. Minimum score of 20/25 in both eyes
 - c. Screen normal color vision (Ishihara Plates)
 - i. *You will view the pages one at a time, while reporting what you see to me. I will let you know when to stop.*
 - ii. Fill in Google Form. Minimum score of 17/21
 - d. If subject is ineligible, skip to Protected Subject Info step and ClinCard step and pay an hour's worth
6. If MwA/MwoA, hand over laptop with pre-session Google Form
- a. BLNK Pre-Session Questionnaire: <https://forms.gle/Sma64f2KrxHudzb9>
 - b. Provide Subject ID and Session Number
7. If MwA/MwoA, collect headache diary and save as Headache Diary.docx in new path
- a. Dropbox/Your_Name/BLNK_data/expt01_summer2023/SubjectID/YYYY-MM-DD/

We are going to go over the main part of the study now. We'll first do a demo run to introduce you to what the stimulus, the air puff, feels like before we start the official runs, also known as scans. The device you see here on the tripod will be used to record your blink response. Here's how this will go: you'll sit on the chair, you'll lean forward, and you'll rest your face into the eye piece there. You won't see anything but, while you look straight ahead, every once in a while there'll be a puff of air that will be directed towards your left or right eye, and you won't know in advance. You won't know exactly when the air puff will occur, and you won't know in which eye the air puff will land. Naturally, you will blink in response to the air puff, but try and hold still. In other words, keep your face resting on the device when the air puff arrives. You may hold onto

the tripod to stabilize yourself if the air puffs startle you. For us to make good measurements, we'll need you to keep your eyes open in between the puffs. Of course, when an air puff lands, you will blink. You might want to blink your eyes for a couple times after each air puff, but **in between** them, try to hold still, keep your eyes open, and look straight ahead. The device will only deliver the air puff when it can see that your eyes are open, so things will go faster if you're able to keep your eyes open and look straight ahead. We have a total of 26 scans and each scan will have 8 puffs of air. Aside from the first demo scan, we'll group the scans into 5 blocks of 5 scans each. We'll complete a block of 5 scans and take a two-minute break. Then we'll complete another block, take another two-minute break, and so on until we're done with all 26 scans. During the break, you can look at your phone, rest your eyes, or use the restroom if you need to, but we'll also ask you to put some eye drops in. The purpose being so that your eyes keep moist since the air puffs can dry out the eyes if no eye drops are used. You'll also be wearing headphones during each scan and I've already wiped them down before your arrival. The headphones will play a type of white noise, a brown noise to be specific, so that you won't hear when the air puffs come. However, because you'll be wearing headphones, it may be a little difficult to understand each other, so we'll need a system to communicate. Here's how that will go: I'll motion like this:

Hand motion

to indicate that you should lean forward and put your face into the device to begin a scan. On the other side of this device, there is a screen where a line will appear and where I'll be able to see your eyes. We'll want to very closely align your eyes to the line that appears on the screen to get the best measurements. So after you've leaned forward and your face is in the eyepiece, I **might** ask you to make very **subtle** movements so that we can be as closely aligned as possible. If I say, "tilt left or tilt right," that means I'm asking you to tilt your head **very slightly** to your left or to your right like this:

Tilt head left/right

If I say, "lift face or lower face," that means I'm asking you to lift or lower your face **very slightly** up or down like this:

Lift face/lower face

When the scan's done, I'll pause the brown noise and that'll be your signal to lean back. Now that we've gone over this communication system, let's practice it. If you see me do this...

Do hand motion and wait for subject to lean forward and put face into the device

Great. And if I say, "tilt left"

Wait for subject to tilt head to their left ever so slightly

Awesome. And if I say, “lower face”

****Wait for subject to lower face ever so slightly****

Perfect. And when the brown noise stops...

****Wait for subject to lean back****

Great! Now remember, I won’t always ask you to tilt your head. I’ll only ask you to do that if the alignment could be improved. Otherwise, the scan will start and the air puffs will too. Any questions for me first about the overall structure of this?

****Pause for any questions****

8. Position subject
 - a. Station tripod across from subject
 - b. Adjust chair up or down
 - c. Ensure subject’s posture to device is fine
9. Brown noise check
 - a. Turn brown noise on at max volume
 - b. Turn headphones’ Bluetooth on by holding down the power button
 - c. Subject puts on headphones
 - d. Pause brown noise
 - e. Ensure noise is loud but not uncomfortable
 - f. Subject takes off headphones
10. Ask subject to use restroom before scan begins
11. If wearing glasses, ask subject to remove them

Now we’re going to do the demonstration. We’ll start with a demo scan where we won’t keep the results. This is to introduce you to what the air puffs feel like and how to be a subject in the experiment. Across scans, sometimes the air puffs will be very weak and other times they will be stronger. You won’t know in advance how strong a scan’s air puffs will be. In this very first scan though, you’ll get the 8 air puffs at a medium strength level. I’ve already wiped down the device before your arrival so we’re good to go. Just do your best to hold still, keep your eyes open, and look straight ahead throughout the entire scan. Remember, you may hold onto the tripod to stabilize yourself.

12. Demo scan: 8 puff sequence at 20 PSI
 - a. Add Date/Time to subject’s [Variable Pressure Scans.pdf](#)
 - b. Headphones on
 - c. Click “scan” or “take baseline”, confirm fake birth date, “Dx”
 - d. Hand motion to lean forward
 - e. Turn on digital meter and adjust variable regulator to 20 PSI
 - i. Note: increase PSI by turning left, decrease PSI by turning right

- ii. Note: when decreasing PSI, first turn variable regulator all the way to the right and pull the pressure release valve to bring PSI back down to 0. Then turn left to reach desired PSI.
- f. Fill out subject's Variable Pressure Scans.pdf
- g. Align eyes
- h. Click "scan" and turn brown noise on
- i. Ensure subject's eyes are open during scan for valid data
- j. When scan's done, bring variable regulator PSI back down to 0
- k. Pause brown noise to lean backward
- l. Ensure a folder was successfully created for the scan
 - i. Desktop/Videos/ (not to be confused with This PC/Videos/)
- m. Click "done"
- n. Headphones off
- o. Ask subject if they found that the air puffs were hitting the equivalent area on each eye
 - i. If subject says no, repeat demo scan at 20 PSI until subject says yes

This completes the demonstration scan. Great job! Throughout the remainder of the study, sometimes the air puffs will be softer than that and other times they'll be a little stronger, but this gives you a pretty good idea of what the experience will be like. Now we have our first two-minute break. One of the things we need to do at the start of every break is give you lubricating eye drops. They're the same kind that you can find at any CVS or pharmacy. These are preservative-free eye drops so we aren't concerned that you'll have an allergic reaction to them. Now, are you the kind of person that can put in eye drops yourself or do you need help with that?

****Wait for subject to respond****

You can do it yourself, great! I'm going to give you the eye drop vial. Just tear off the little plastic tab at the top and I'll hand you the tissue box in case you need it. Then you'll go ahead and lean back and put the drops in yourself. I'll watch just to make sure that a drop gets in there.

No worries, I'll help you put those in! Here's what you'll do. You'll take this tissue box in case you need it. Then you'll use one finger to pull down your lower eyelid gently, lean your head back, and I'll put an eye drop in. If it helps, you can look to the side. And then we'll do the other eye. Then we'll take the rest of the break time and start the first block of 5 scans.

****Two minutes elapse****

13. Eye drops

- a. Start timer
- b. Provide eye drops and tissue box
- c. Confirm with subject that we were able to get an eye drop in each eye

14. Repeat x5

- a. Headphones on
- b. A block of 5 scans at different pressures: 0, 5, 10, 20, or 40 PSI
 - i. A single scan (8 puff sequence)
 1. Click “scan”, confirm fake birth date, “Dx”
 2. Hand motion to lean forward
 3. Turn on digital meter and adjust variable regulator to desired PSI
 - a. Note: increase PSI by turning left, decrease PSI by turning right
 - b. Note: when decreasing PSI, first turn variable regulator all the way to the right and pull the pressure release valve to bring PSI back down to 0. Then turn left to reach desired PSI.
 4. Fill out subject’s *Variable Pressure Scans.pdf*
 5. Align eyes
 6. Click “scan” and turn brown noise on
 7. Ensure subject’s eyes are open during scan for valid data
 8. Bring variable regulator PSI back down to 0
 9. Pause brown noise
 10. Ensure a folder was successfully created for the scan
 - a. *Desktop/Videos/* (not to be confused with *This PC/Videos/*)
 11. Click “done” and repeat until block ends
 - c. Headphones off
 - d. 2-minute break (eye drops)
 - i. Start timer
 - ii. Provide eye drops and tissue box
 - iii. Confirm with subject that we were able to get an eye drop in each eye
15. Turn headphones’ Bluetooth off by holding down the power button
16. Subject can put glasses back on
17. Hand over laptop with debrief Google Form
 - a. BLNK Debrief: <https://forms.gle/Ec5JAprS6BsMyXnS8>
 - b. Provide Subject ID and Session Number

To set a payment, we need to collect some information from you. Some of this information is your private, personal, and/or identifying information. I’ll enter the information into our database, which is password-protected and is not linked in any way to the data that we’ll collect from you as part of the study. That way, when our research study ends, we can release the data that we collect without linking it to you or releasing any of your private personal information. We will do our absolute best to keep this private and protected, only within our systems here at the University of Pennsylvania.

18. Open the *Protected Subject Information Template.docx* and fill in subject’s info
 - a. *Box/BLNK_protected/Protected Subject Information Template.docx*
19. ClinCard
 - a. Register subject

- i. Click on “Register Subject” and select the study
 - ii. First/Last name, DOB, and address are required
 - iii. Fill in all required fields
 - iv. When you click “Register”, the system will bring you into their profile
 - b. Assign the ClinCard
 - i. Click on “Assign ClinCard”
 - 1. Ask if they’d prefer a physical or virtual card
 - 2. If physical card, enter the Token# located in the window on the front of the envelope. Click “Assign”
 - 3. If virtual card, enter the email address and click “Send”
 - c. Load a payment
 - i. Click on “Request Payment” and choose the correct payment milestone. You can also use “Miscellaneous Payment”, but a brief note is required
 - ii. Note: You can check your study budget by clicking on the “Reports” tab in the ClinCard system and then click on “Study Budget Report.” You can see Budget, Total Payments, and Remaining Budget.
- 20. If MwA/MwoA, ask subject to keep an eye out for the last Google Form, which will be sent out in 5 days. They should complete it 5-7 days after today’s session.
 - a. BLNK Post-Session Questionnaire
- 21. Walk subject out

After Visit:

- 1. Delete demo scan’s video data files
- 2. EyeStat device data handling
 - a. (Device -> Hard Drive) After a complete session, transfer the blink video data files from the EyeStat device onto the external hard drive (Blink 030).
 - i. EyeStat device directory: Desktop/Videos/ (not to be confused with This PC/Videos/)
 - ii. External hard drive directory: This PC/Blink 030/EyeStat Recordings/
 - b. (Device + Hard Drive -> BlinkCNS) Upload the video data files from the EyeStat device to BlinkCNS folks with the external hard drive still connected to the EyeStat device.
 - i. Click the back arrow, click the X to exit out of search, click the back arrow, click on the hamburger menu
 - ii. Next to “Upload Video Files”, click on “Upload”
 - c. Empty EyeStat device storage (can empty only if external hard drive has the files).
 - d. (Hard Drive -> Dropbox) Upload the video data files from the external hard drive to the lab Dropbox.
 - i. Dropbox/Your_Name/BLNK_data/expt01_summer2023/SubjectID/YYYY-MM-DD/
 - e. Empty external hard drive storage (can empty only if Dropbox and BlinkCNS folks have the files).
- 3. Turn off EyeStat device
 - a. Click on the hamburger menu
 - b. Click “Logout”

- c. "Shut down" device
 - d. Disconnect external hard drive and keyboard from EyeStat device
 - e. Disconnect power cable from EyeStat device
4. Transfer the Protected Subject Information Template.docx info into the BLNK protected subject info.xlsx excel sheet and fill in any extra session notes
 - a. Template directory: Box/BLNK_protected/Protected Subject Information Template.docx
 - b. Excel sheet directory: Box/BLNK_protected/BLNK protected subject info.xlsx
 - c. Clear out all the personal info from the template document
5. Clean up room
 - a. Log out of ClinCard and close Chrome
 - b. Wipe headphones
 - c. Place headphones back in their case and charging
 - d. Wipe EyeStat device (only the outer rim of the eye piece)
 - e. Station tripod back in between the two tables
 - f. Turn keyboard switch off
 - g. Plug laptop
 - h. Exit out of all documents on laptop
6. Pack
 - a. If subject didn't choose a physical ClinCard, store it again
 - b. Ishihara Plates
 - c. Consent form
7. Scan consent form with USB Scanner and store it in Box as a PDF
 - a. Box/BLNK_protected/expt01_summer2023/consentForms/ICF_SubjectID.pdf
 - b. Password protect the scanned PDF
 - c. Shred the physical consent form
8. Note major events, if any (when data from the first subject is collected, if it is necessary to change an aspect of the experiment once it has started, if a subject is excluded for some reason, etc.)
 - a. Dropbox/Your_Name/BLNK_admin/Summer2023Expt_MajorEvents.txt
9. If Mwa/MwoA, set reminder to send subject the last Google Form in 5 days
10. Email BlinkCNS
 - a. Let them know we've uploaded to them and ask for the A File and Summary sheets with the 25-90 ms ruleset for the new data.
 - b. Update: Ask for improved I-Files and Opening parameter.