Day of Visit Protocol

Necessary Materials:

- Tissues
- Hand sanitizer
- Sanitizing wipes
- Lubricant eye drops
- 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 green 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

<u>Subject Activity:</u>

1. Sanitize hands
2. Add Date/Time to subject's `Variable Pressure Scans.pdf`

Welcome and thank you very much for participating in our study! 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, which was also emailed to you. I'll have some additional forms and screening information to collect from you as well. 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 the 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. Feel free to look through the consent form again. If you have any questions about the contents of it, I'll do my best to try and answer them for you. Otherwise, we can go ahead and sign the form.

****Hand over consent form and pen****

3. Sign the printed IRB stamped consent form
4. In-person screening (check appearance of eyelids)
    a. *I'll now look at your eyes and check that your eyelids move fully.*
       Gently close your eyes.
       Now gently open your eyes.
    b. 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?
    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 best **corrected** visual acuity (Snellen Chart)
        i. Box of trial spectacles (if subject does not bring their glasses)
            1. *Do you think you need glasses to see better at a distance? Would you want to try some glasses to check?* If they answer "yes", have them try a +1 and a -1 set of spectacles and see if either improves their vision. If so, pursue different levels of correction on the plus or minus side until they report that they can see better. Nearsighted people generally have trouble with the Snellen Chart at a distance and will need minus lenses to correct their vision.
            2. If they answer "no" and they have trouble with the Snellen Chart, have them try glasses and see if they can do better
        ii. Ensure overhead lights are on
        iii. *Please stand on the black line, which is 20 feet away from the Snellen chart, for measurement of your visual acuity. Wear any corrective glasses you regularly use for your vision and 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 repeat this process with the other eye, after.* 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.
        iv. 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 inside this book 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/Sma64f2KrxcHudzb9
    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're 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 or 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. We ask that you hold onto the tripod to stabilize yourself as the air puffs may startle you. For us to make good measurements, we'll need you to keep your eyes open in between the puffs. Of course, you will likely blink when an air puff arrives, but ***in between*** *the puffs, 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 breaks, you can rest your eyes, look at your phone, or use the restroom, 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 wear headphones during the scans; they've been wiped 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. It may be tough to hear me with the headphones on, so we'll need a system to communicate. Here's how that will go: If I say, "lean forward," that means I'm asking you to lean forward and place your face in the device eyepiece to begin a scan. On the other side of this device, there is a screen where I'll be able to see your eyes. A line will display and we'll want to align your eyes to that line 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, tilt right, tilt up, or tilt down," that means I'm asking you to tilt your head* ***very slightly*** *to your left, your right, up, or down like this:*

****Tilt head left/right and tilt head up/down****

If I say, "turn left or turn right," please turn your head ***very slightly*** *to your left or right like this:*

****Turn head left/right****

If I say, "go up or go down," that means lift or lower your head ***very slightly*** *up or down like this:*

****Go up/go down****

When a block of 5 scans is done, I'll say, "lean backward," and that'll be your signal to lean back and remove your face from the device eyepiece. I will pause the brown noise when I need to

communicate with you but, if possible, please do not lean back until I specifically say, "lean backward." This might be a lot to remember, so now that we've gone over this communication system, let's practice it. If I say, "lean forward"

****Wait for subject to lean forward****

Great. And if I say, "tilt left"

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

Good. What if I say, "turn left"

****Wait for subject to turn head to their left ever so slightly****

Awesome. And if I say, "tilt down"

****Wait for subject to tilt head down ever so slightly****

Good. What if I say, "go down"

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

Perfect. And when I say, "lean backward"

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

Great! Now remember, I won't always ask you to tilt or turn your head, only if the alignment could be improved. Otherwise, the scan will start and the air puffs will too. Any questions?

****Pause for 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'll start the demo scan, where results won't be kept. This will introduce you to what the air puffs feel like and how to be a subject in the study. Across scans, sometimes air puffs will be very weak and other times they'll be stronger. You won't know in advance how strong a scan's puffs will be. In this demo scan, you'll get the 8 air puffs at a medium strength level. The device has been wiped down before your arrival. Just do your best to hold still, hold onto the tripod to stabilize yourself, keep your eyes open, and look straight ahead throughout the entire scan.

12. Demo scan: 8 puff sequence at 20 PSI
    a. Headphones on
    b. "Lean forward" and turn brown noise on
    c. Click "scan" or "take baseline", confirm fake birth date, "Dx"
    d. Turn on digital meter and adjust variable regulator to 20 PSI
        i. Note: turning left increases PSI, turning right decreases PSI
        ii. Note: when decreasing PSI, first turn variable regulator all the way to the right and pull the pressure release valve to bring PSI down to 0. Then turn left to reach desired PSI.
    e. Fill out subject's `Variable Pressure Scans.pdf`
    f. Align eyes (brown noise pause/resume)
    g. Click "scan"
    h. Ensure subject's eyes are open during scan for valid data
    i. When scan's done, bring variable regulator PSI back down to 0
    j. Ensure a folder was successfully created for the scan
        i. `Desktop/Videos/` (not to be confused with `This PC/Videos/`)
    k. Click "done"
    l. Pause brown noise and say, "lean backward"
    m. Headphones off
    n. Ask subject if puffs were hitting the symmetrically equivalent area on each eye
        i. If subject says no, repeat demo scan at 20 PSI until subject says yes

This completes the demo 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. At the start of every break, we'll give you lubricating eye drops. They're the same kind you'll find at any CVS or pharmacy. They're preservative-free eye so we aren't concerned you'll have an allergic reaction to them. Are you able to put in eye drops yourself or would you like some help?

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

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

No worries, I'll help you put those in! Here's a tissue box in case you need it. Use a 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. Then we'll do the other eye 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 block x5
    a. Headphones on
    b. "Lean forward" and turn brown noise on
    c. Repeat scan x5 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. Turn on digital meter and adjust variable regulator to desired PSI
                a. Note: turning left increases PSI, turning right decreases PSI
                b. Note: when decreasing PSI, first turn variable regulator all the way to the right and pull the pressure release valve to bring PSI down to 0. Then turn left to reach desired PSI.
            3. Fill out subject's `Variable Pressure Scans.pdf`
            4. Align eyes (brown noise pause/resume)
            5. Click "scan"
            6. Ensure subject's eyes are open during scan for valid data
            7. When scan's done, bring variable regulator PSI back down to 0
            8. Ensure a folder was successfully created for the scan
                a. `Desktop/Videos/` (not to be confused with `This PC/Videos/`)
            9. Click "done" and repeat until block ends
    d. Pause brown noise and say, "lean backward"
    e. Headphones off
    f. 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 which is your private, personal, and/or identifying information. I'll enter it into our database, which is password-protected and 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'll 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. Fill in all required fields
        iii. When you click "Register", the system will bring you into their profile
    b. Assign the ClinCard
        i. Click on "Assign ClinCard"
        ii. Ask if they'd prefer a physical or virtual card
        iii. If physical card, enter the Token# located in the window on the front of the envelope. Click "Assign"
        iv. 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

<u>After Visit:</u>

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. In the application, 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.xlsl` 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.xlsl`
    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 (data from first subject is collected, if it’s necessary to change an aspect of the experiment once it has started, if a subject is excluded for some reason)
    a. https://github.com/gkaguirrelab/preregistrations/blob/master/blink_2023/README.md
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 Summary sheets with the 25-90 ms ruleset for the new data.
    b. Update: Ask for improved I-Files, which should include the Opening parameter at the time of each air puff trial (i.e., the upper and lower lid positions).