Martinos Center for Biomedical Imaging STANDARD OPERATING PROCEDURE Human Subject Imaging Safety in Response to COVID-19

June 11, 2020

HIGHLIGHTS

PI has an approved Work Plan

Onsite staff have completed one-time Onsite Research Attestation

Onsite staff complete daily attestation – "Covid Pass"

Remote completion of: Informed Consent, study questionnaires/paperwork and PET/MR Safety Screening

Remote Covid 19 Screening within 24 hours of scan and repeated upon arrival

Staff and Subject don fresh masks upon arrival to be worn continuously

Staff and subject frequently sanitize hands

Disinfection of shared/frequently touched surfaces/equipment

Read SOP in its entirety

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PURPOSE:

To describe safety precautions to be taken during imaging of human subjects to prevent the spread of COVID-19

DESIGNATED AREAS:

- Bays1-8
- MEG Laboratory

LEVEL OF PERSONNEL:

- Martinos Core Staff
- Study Staff

POLICY STATEMENT:

- The spread of COVID-19 is reduced by using appropriate PPE, social distancing, limiting close-proximity interactions, sanitizing equipment/surfaces, avoiding group gatherings and screening people for risk factors. These measures must be taken to reduce the spread of COVID-19 during imaging procedures
- Guidelines will be in line with those issues by state and local authorities and MGB
- This document is subject to change

CRITICAL ELEMENTS:

- For the duration of the imaging visit, one staff member will be considered "interactive" and the other will be "passive" The "interactive" staff member will be in contact with the subject and the "passive" staff member shall only have contact with the subject in the case of a medical emergency.
- One study staff member and one core staff member will be present for the scan

- Scans will be scheduled at least 15 minutes apart to allow for adequate cleaning and to avoid group gatherings and intermingling
- Only indicated PPE provided by the center shall be worn
- Gloves will be worn as needed to perform medical procedures. Gloves will be removed upon completion of medical procedures or cleaning tasks and are not to be worn continuously.

PROCEDURE:

1) Prior to scanning:

- Study Staff will complete Informed Consent with IRB approval, all safety screening and COVID-19 screening (Appendix A) with the subject via phone call within 24 hours of the imaging appointment
- Study Staff will advise subjects to arrive at Martinos 15 minutes prior to their scheduled scan time
- Study Staff will advise subjects to come alone to the scan unless the
 subject is a minor or dependent adult, in which case one parent or legal
 guardian will be allowed to accompany the subject. If friends or family
 members transport the subject to their appointment, they will be advised to
 wait in the car and provide a phone number where they can be reached when
 the scan is completed.

2) Upon subject's arrival:

- One person, either a core staff member or a study staff member, will be designated as "interactive" Wearing a surgical mask, the "interactive" staff person will greet the subject at the security desk in the lobby of building 149.
 If the subject needs assistance walking or requires a wheelchair, they will be met in front of the building or in the parking garage.
- At the mask station in the lobby of building 149, the subject and staff
 person will apply hand sanitizer and the subject will don a fresh mask per
 the instructions provided at the mask station. Subject will wear this mask for
 the duration of the scan visit unless otherwise indicated in this document. The
 subject will also take the paper bag provided at the mask station for
 mask storage during scanning.
- Before proceeding to the scanning area, staff will confirm with the subject that nothing has changed regarding their COVID-19 screening and the

scan safety screening since the telephone screening was completed less than 24 hours prior to the subject's arrival.

3) Scan preparation:

- After the subject has received the appropriate PPE and attested to the COVID
 19 and scan safety screenings, the "interactive" staff member will lead the
 subject to a changing room, where the subject will change into a hospital
 gown, pants, robe and slippers while wearing their surgical mask.
- Staff will take personal items from the subject and store them in a locker for the duration of the scan
- If needed, the subject will use the bathroom adjacent to the changing room before entering the screening area.
- If IV placement is required for scanning purposes, the subject will be brought to the IV station where a core staff member will place the IV. Prior to placing the IV, staff will wash and sanitize hands.
- If IV is not needed, the subject will be led directly to the magnet room
- Upon entering the scanner/magnet room, staff will again sanitize their hands and will don protective goggles
- Staff will set the bore fan on the highest setting before placing the subject on the table
- The subject will remove their mask and place it in the bag provided by the mask station and leave it in a designated area in the scanner room so that it can be donned immediately after scanning is completed.
- The subject is placed on the scanning table and provided with ear plugs, back support and extra padding/support as needed for comfort.
- A squeeze ball will be placed next to the subject's hand, and the subject will be instructed to squeeze the ball should they need to communicate with staff urgently, such as in the case of an emergency
- Staff will place the head coil, adjusting the mirror as needed for visual paradigms.
- Staff will place the button box close to the subject's hand, if needed and instruct the subject as to its use.

- Staff will move the table into the scanner and confirm that the subject is comfortable.
- Staff will sanitize their hands again, either before leaving the scanning room or immediately after leaving the scanning room, upon entering the control area.

4) During scanning:

- The "passive" staff person will start scanning.
- Meanwhile, the "interactive" staff person will sanitize the changing room used by the subject and the bathroom as needed with the provided sanitizing supplies. Surfaces to be sanitized include doorknobs/handles, light switches, toilet flush handle, sink faucets, locker handles and all other surfaces the subject potentially touched
- After cleaning, the "interactive" staff person will sanitize their hands and return to the control room to assist with the scan as needed, maintaining a six-foot distance from other people present in the control room. Staff will be mindful of the floor markers designating the appropriate distance.

5) After the scanning is completed:

- The "interactive" staff person will remove the subject from the scanner
- Upon entering the scanner room, staff will sanitize their hands and apply protective goggles if the subject chose not to wear a mask during the scan
- The **subject will be instructed to don their mask immediately** after getting up from the scanning table
- Staff will escort the subject back to the changing area and retrieve the subject's belongings from the locker.
- Staff will wait for the subject to change, and then escort them to the lobby area. If needed the staff person will assist the subject in getting safely to the car.

6) Post Scan Clean-Up:

- The "interactive" staff member will **again sanitize the changing area and bathroom as needed**
- Core staff and study staff will sanitize the magnet room and the control room using "3M Neutral Quat Disinfectant Cleaner Concentrate 23A"

- Cleaning solution will be applied to a paper towel and not directly on the equipment
- Areas to be sanitized include but are not limited to the following:

Magnet Room

- Inside the coil
- table mattress
- button box
- squeeze ball
- o scanner control buttons on the face of the scanner
- inside the bore staff will spray cleaning solution on a Swifter Duster and, using the plastic extension handle provided, wipe the inside of the bore with the duster.
- o counter tops
- door handle
- any/all other surfaces touched by staff or suject

Console Area

- Keyboard
- o Mouse
- Table/counter/desktop
- o Phone as needed
- Arms of the chairs
- Door handle
- Cable connections as needed
- Any/all other surfaces that were touched
- Staff will *close doors* to the magnet and the control rooms after cleaning is completed

EQUIPMENT:

- Surgical Masks
- Protective goggles
- Cleaning supplies:
 - o 3M Neutral Quat Disinfectant Cleaner Concentrate 23A
 - Sani cloths
 - Virex

DEFINITIONS:

COVID-19: Cornavirus Disease of 2019

- MEG: Magnetoencephalography
- PPE: Personal Protective Equipment
- IRB: Internal Regulatory Board
- PET: Positron Emission Tomography
- MR: Magnetic Resonance
- IV: Intravenous

REFERENCES:

REVISION DETAIL:

Version 1 approved by: Martinos Safety Committee May 20, 2020

Appendix A

COVID-19 Subject Screening

1)	ave you traveled outside of the US in the last 30 days?	
	YES	NO
2)	Have you had a fever or felt feverish in the last 24 hours?	
	YES	NO
3)	Have you had contact with a known or suspected case of COVID-19	
	YES	NO
4)	o you have trouble breathing or a new cough?	
	YES	NO
5)	Are you having nausea, vomiting or diarrhea?	
	YES	NO
6)	Do you have a new rash?	
	YES	NO
7)	Do you have the following new symptoms? (Circle all that apply)	
	Sore throat Muscle aches Severe dizziness or fainting Anosmia (change in sense of smell) Chest Pain Nasal Congestion None	