NYSPI MRI RESEARCH PROGRAM

COVID-19 RAMP-UP & REACTIVATION PLAN

Phase I
SCANNING CAPACITY & REACTIVATION

PRE-COVID19

Before the pandemic, the NYSPI MRI unit operated from 8am to 8pm Monday-Friday and 9am-5pm as needed on Saturday and Sunday, averaging up to 45-60 scans per week (7-10 scans per day) depending on session length.

POST-COVID19

As the MRI Unit reactives, we are doing so with the goal of minimizing the risk to both staff and participants. In order to allow ample time for disinfection and newly-instituted safety protocols and procedures, we must reduce the operating capacity of the scanner and restrict access to the MRI unit. All protocols have been carefully considered and reviewed by Administrative and Clinical Faculty for efficacy and safety.

During Phase I of the MRI Unit reactivation, the scanner will be limited to approximately 3-4 scans per day depending on session length. The operating hours will be condensed to limit the MRI operator’s potential exposure and to allow for post-operation cleaning protocols at the end of each day.

As we progress through the initial phases of ramp-up and reactivation, we will continue to revisit and evolve our procedures and work to expand capacity. We will update and revise these procedures accordingly.

The most current version of this document will be made available on the NYSPI MRI website at https://nyspi.org/mri
SUMMARY OF PROCEDURES

When the IRB and NYSPI Administration make the determination that the MRI imaging at NYSPI is able to ramp-up operations and resume scanning, we will proceed following all guidance and institutional recommendations and requirements to ensure the safety of both staff and participants.

What follows in this manual is a detailed overview of the operating procedures of the MRI during the initial phase of resuming operation, which includes:

Participant and Staff Screening

- All participants will be screened for COVID-19 symptoms according to institutional guidelines upon entrance to NYSPI, including temperature and other symptoms of illness.

Social Distancing

- The MRI suite will strictly limit the number of people in the facility at any time in order to maintain appropriate social distancing.
- Staff should arrive with participants as close to the scan time as possible to minimize time in the suite, preferably no more than 15 minutes to allow for prep procedures.
- No one other than the scanning RA should accompany participant unless they require special assistance.

PPE

- All participants and staff must wear masks while in the suite. Additional Masks and sanitizer will also be provided in the MRI suite.
- During the scan, wearing a mask is optional for the participant based on comfort level and to minimize the potential for motion artifacts due to discomfort during scanning.

Cleaning & Disinfecting

- The MRI suite will be cleaned and disinfected routinely in partnership with environmental services, paying special attention to frequent contact surfaces.
- All imaging equipment will be cleaned and disinfected between each participant.
The MRI Research Program scanning suite at NYSPI is a shared resource dedicated to the acquisition of brain imaging for the purpose of psychiatric research, much of which is done in conjunction with beneficial clinical treatment for participants. The suite is located on the S-Level of the Pardes Building and houses a GE Premier 3T research-dedicated MRI.

This document describes an overview of the proposed policies and procedures for the ramp-up and reestablishment of image acquisition at this facility when deemed to be at an appropriate stage for doing so during the COVID-19 pandemic while remaining consistent with the institutional health and safety guidelines as well as Institutional Review Board guidance. The policies in this document are to be followed rigorously to ensure absolute minimal COVID-19 transmission risk. All research group scan personnel will be required to undergo training and review all procedures before being allowed to resume scanning.
REMOTE SCREENING

The day before arrival at NYSPI, all participants (and/or guardian(s)) will be asked via phone/video conference the following questions by the study group:

1. Has anyone in your household tested positive for COVID-19? If yes, when?

2. Have you tested positive for COVID-19? If yes, when?

3. Has anyone in your household experienced any of the following symptoms in the last 14 days? Coughing, shortness of breath or difficulty breathing, fever, chills, muscle pain, sore throat, loss of taste or smell or illness of any kind? If yes, please describe.

4. In the past 14 days, have you experienced any of the above symptoms? if yes, please describe.

If participants or guardian(s) answer “yes” to any of the above, the visit to NYSPI may be delayed.

ARRIVAL AT NYSPI

Visitors will follow all institutional guidelines for entry, which may include no-contact temperature checking and screening for symptoms. Only visitors who pass screening criteria may proceed.

THE MRI UNIT

Access to the MRI Unit will be restricted in order to limit the number of staff in the suite at any given time, as well as to account for frequent cleaning & disinfecting. Participants and study group personnel may only enter the suite via the “GROUP ENTRANCE” and exit via the “GROUP EXIT” without exception. Signs will be placed at each entry and exit point.

Environmental services will partner with MRI Unit to institute a morning cleaning routine for deep cleaning and disinfecting frequently touched surfaces. The MRI Operator will also clean and disinfect the magnet room each morning before scans begin.
In order to limit surface contact and reduce the potential for contamination, we ask that all subject paperwork (Metal screener, pregnancy screener etc.) be completed via the MRI REDcap link on the NYSPI MRI website and a PDF copy of the completed survey emailed to the MRI operator on duty along with verification of the signed study consent. When necessary, participant pregnancy tests should be administered before arriving in the MRI suite following procedural guidance from the Infection Control Nurse. We ask that these not be done in the MRI suite at this time.

Upon entry to the MRI Suite via the GROUP ENTRANCE, a table will be available with hand sanitizer, nitrile gloves, and procedural masks. If not wearing one already, research staff should don a mask after using sanitizer, and offer a mask and sanitizer to participants. Participants and staff will be expected to wear masks at all times while in the MRI suite, as well as maintain appropriate social distancing when possible. Only one research staff member will be allowed with the participant and under no circumstances should additional family members or additional staff accompany participant into the MRI suite unless special assistance is required. If additional family or staff are needed for this purpose, please clear and verify with the MRI unit prior to the scan.

Research staff may not bring any superfluous personal belongings or food into the MRI suite. Only items considered essential to scanning may be brought into the suite (laptops, notebooks, etc). Cell phones are allowed.

Participants will be given single-use plastic bags in which to store their extra clothing and belongings and will be given a gown if requested. The dressing and locker room will not be used. Participants will change in the restroom, at which point they will be expected to wash their hands according to CDC guidelines and put all extra belongings in the provided bag, which will then be tied or otherwise sealed. Participants will not be allowed to bring their own bags or purses to the MRI suite, however small essentials (wallet, keys, phone, etc,) are allowed. After changing, participants will exit the restroom with the sealed bag and wait for research staff before proceeding.

While maintaining social distance as much as possible, research staff will escort the participant directly into the ON DECK area, where they will await further instruction from the MRI Operator.

Procedural masks will be provided for participants and research staff, however research staff may use their own n95 masks if they wish.
SCAN PREP

The Research staff member and participant will wait in a designated area in the ON DECK space. The participant will place their sealed bag of belongings in a designated area where it will remain for the duration of the scan, which will be cleaned between scans.

If button box peripheral(s) are needed, the MRI operator will retrieve them for the research staff member after cleaning them with Sani-cloths.*

*Note - if placing peripherals or physiology - the research staff member should don gloves before entering the SCANNER ROOM.

The MRI Operator will then escort the research staff member and participant into the SCANNER ROOM while maintaining social distance as much as possible, at which point the participant will be placed on the scan bed and given relevant instruction and the peripherals and physiology equipment placed as necessary. Any additional padding or material used will be cleaned with Sani-cloths prior to placement.

Participants may be given the option to remove or keep their mask during scanning depending on comfort level. Participants may find wearing a mask for 1 hour or more uncomfortable and may generate movement artifacts. Note: Participants could undergo greater viral exposure and present greater exposure to staff and other participants with masks off during their scan.

The MRI Operator will and research staff member will exit the SCANNER ROOM while continuing to maintain social distance. After exiting the room, the Research staff member may discard their gloves in the trash receptacle (unless soiled, in which case they will be placed in a biohazard receptacle) and immediately use hand sanitizer. The RA desk area will be disinfected with Sani-cloths prior to each scan session.

POST SCAN

After the completion of the scan, the MRI Operator and research staff member will don gloves and the MRI Operator will escort the research staff member into the SCANNER ROOM. The participant will be removed from the scan bed, given a new mask if needed, and the research staff member will discard their gloves and they and the participant will immediately exit the room. The participant will retrieve their bag of belongings and proceed directly to the restroom to change back into their clothing, at which point the gown will be placed into a soiled laundry bin and the plastic bag will be discarded in the trash bin. The participant will wash their hands following CDC guidelines and exit the restroom.

The research staff member and participant will immediately exit the suite via the GROUP EXIT.
THE MRI OPERATOR

The unit will be staffed with a single MRI Operator at any given time, dependent on ability to avoid public transit and prevent overlap. Upon arrival, the MRI Unit operator will change into clean scrubs and their belongings stored. The MRI Operator will be screened at NYSPI entry point for COVID-19.

MRI Unit staff who interact directly with participants will wear MRI-compatible N95 masks as well as face shields to help mitigate the risk of infection due to closeness with participants, handling of peripherals and disinfection of MRI equipment.

Before scans begin, the MRI Operator will disinfect and clean the Console area, RA Desk, and SCANNER ROOM following the procedures outlined below.

CLEANING PROCEDURES

Before opening and after closing, the MRI suite will be deep cleaned and disinfected following a plan designed in partnership with Environmental Services and Infection Control. All contact surfaces (doorhandles, faucets, seating, etc.,) will be given particular attention.

In addition to this, the following methods will be used by the MRI Operator to clean and disinfect scanner equipment between participants.

Restroom and Participant Prep Area
- Door handles and contact surfaces cleaned with Sani-Cloth wipes
- Verify appropriate disposal of any discarded material

Mock Scanner (if used)
- Remove soiled linen
- Wipe down all padding, coils, table, cushion with Sani-Cloth wipes.
- Use Swiffer with Sani-Cloth wipe to clean inside of bore.
- Verify clean linen is available

RA Desk and Scanner Control Console
- Keyboard, mice, desk areas cleaned with Sani-Cloth wipes and appropriate surfaces cleaned with disinfectant spray.
- Any additional surfaces touched during scan wiped down with Sani-cloth wipes.
Scanner Room

- Clean the MRI tables **before and after** each subject with Sani-Cloth wipes
- Clean all pads and positioners **before and after use** with Sani-Cloth wipes
- Look at all pads and positioners for tears or fraying and discontinue use of any damaged pads
- Clean all coils inside and out **before and after each use** with Sani-Cloth wipes.
- Clean all equipment **before and after each use** including but not limited to bellows, physio, headphones, door handles, peripherals, etc.
- Replace linens **before subject use and after room cleaning**, and discard used linens immediately **after subject use before room cleaning**.

SCHEDULING

The following criteria will apply for groups scheduling under the initial ramp-up of MRI scanning activities at NYSPI.

- Until further notice, groups will no longer schedule their own scans. As studies are approved to resume on a case-by-case basis, groups will coordinate with Rachel Marsh and Joe Figliolia to assign days and time(s) for scans.

- There will be a one hour gap between scans to allow for thorough cleaning of the space between subjects which will be scheduled on the calendar as part of a group’s time. Groups will not be charged for this additional cleaning time.

- Normal cancellation fees will apply under the normal cancellation policy.

- Before being allowed to scan, research staff will receive a thorough review of all existing safety policies as well as training and review of new COVID-19 related procedures, including a dry-run without a subject.
**ESTIMATED PPE REQUIREMENT**

Assumes initial ramp-up rate of 3-4 scans daily

<table>
<thead>
<tr>
<th>Number of Scans</th>
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<tbody>
<tr>
<td>Daily Scans</td>
<td>4 x 5</td>
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<tr>
<td>Weekend Scans</td>
<td>4 x 2</td>
</tr>
<tr>
<td>Weekly</td>
<td></td>
</tr>
<tr>
<td>Total Scans Monthly</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Supplies Per Scan</th>
<th></th>
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<tbody>
<tr>
<td>Gloves (pairs)</td>
<td>RA, Operator</td>
</tr>
<tr>
<td>Procedural Masks</td>
<td>RA, Participant</td>
</tr>
<tr>
<td>Sanitizer</td>
<td>5mL pump/10 pumps</td>
</tr>
<tr>
<td>Sani-Cloths</td>
<td>Squeeze ball, Console, Bore, Coil, Cushions, Hard Surfaces, Chair arms, Door Handles, Restroom</td>
</tr>
<tr>
<td>Gown (as needed)</td>
<td>Subject</td>
</tr>
<tr>
<td>Clean Scrubs</td>
<td>Operator</td>
</tr>
<tr>
<td>N-95 Mask</td>
<td>Operator</td>
</tr>
<tr>
<td>Face Shields</td>
<td>Operator</td>
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</table>

<table>
<thead>
<tr>
<th>Estimated Monthly Need</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Masks</td>
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</tr>
<tr>
<td>Gloves</td>
<td>50 Pairs/Box</td>
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<td>Sani-Cloth Wipes</td>
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<tr>
<td>Hand Sanitizer</td>
<td>2 pumps per use</td>
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<tr>
<td>N-95 Masks</td>
<td>5 per operator</td>
</tr>
<tr>
<td>Face Shields</td>
<td>1 Shield</td>
</tr>
</tbody>
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All Policies/Procedures in the preceding document are subject to change based on conditions and ongoing evolution of Institutional and NY State policies and recommendations.