



THE
NYSPI MRI
RESEARCH PROGRAM

COVID-19 RAMP-UP & REACTIVATION PLAN

Phase II- rev1

SCANNING CAPACITY & REACTIVATION

PRE-COVID19

Before the pandemic, the NYSPI MRI averaged up to 45-60 scans per week (7-10 scans per day) depending on session length.

POST-COVID19

As the MRI Unit reactivates, 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.

We are currently in Phase II of MRI Unit Reactivation. The scanner is currently operating at 50-70% of normal capacity on any given day depending on number of scan sessions, session length, etc. Operating hours are back to normal as of 9/1/2020.

Through the initial phases of ramp-up and reactivation, we've revisited and evolved several of our policies and procedures as we've acclimated to the current environment, and we will continue to do so. This guide will be updated and revised 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. Participants and Faculty & Staff are required to complete online questionnaires before their arrival at NYSPI.

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. groups will be expected to adhere to their time slots and will not be allowed to run over.
- 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

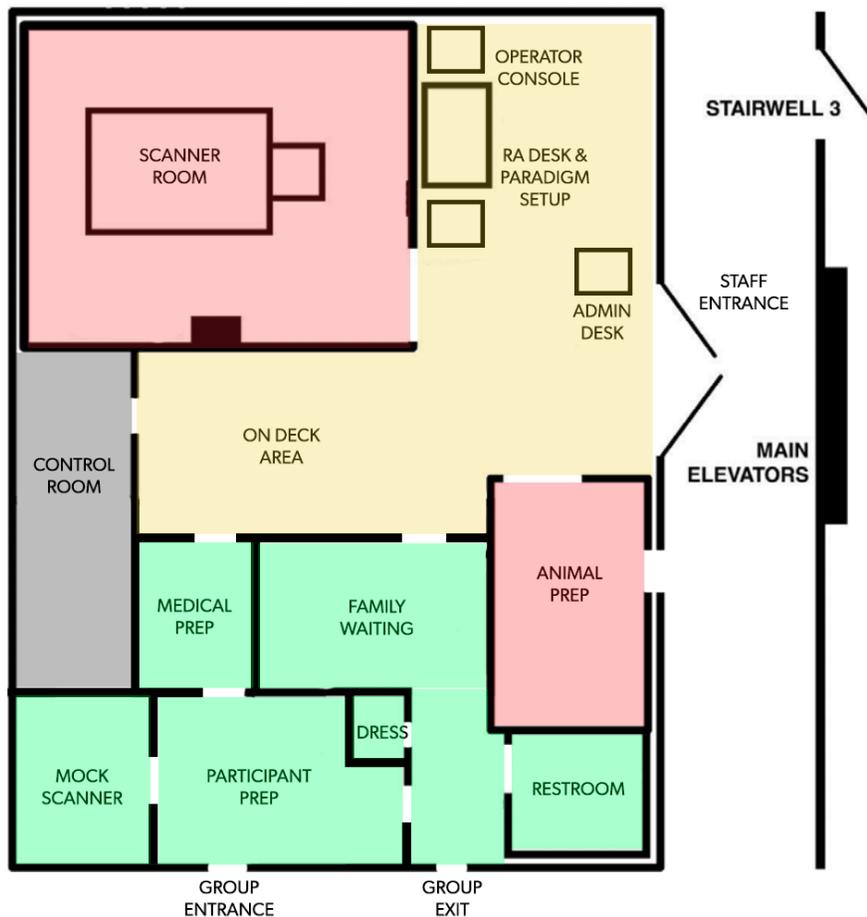
- The MRI suite will be cleaned and disinfected routinely in partnership with environmental services, paying special attention to frequent contact surfaces
- All imaging equipment used in a scan will be cleaned and disinfected between each participant

INTRODUCTION

The MRI Research Program scanning suite at NYSPI is 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.

THE NYSPI SCANNING SUITE



PRE SCREENING

NYSPI Requires that all Faculty, Staff, Research Participants and any accompanying visitors complete the online screening questionnaire before arriving at NYSPI. If coming on site for an MRI, the screening approval will automatically be forwarded to the MRI Unit staff. Participants who have not completed this questionnaire will be denied admittance to the unit.

The research participant questionnaire is located at:

<https://rc-1.nyspi.org/surveys/?s=EDPYT4DFRM>

The faculty & staff questionnaire is located at:

<https://rc-1.nyspi.org/surveys/?s=PEE894HHDE>

Participants and/or Faculty & Staff may be denied entry to NYSPI dependent on answers given.

ARRIVAL AT NYSPI

Visitors will follow all institutional guidelines for entry, which will include no-contact temperature checking and masks must be worn at all times. 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.

PARTICIPANT ENTRY & PREP

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 and fillable PDF links on the NYSPI MRI website and a PDF copy of the completed forms emailed to the MRI operator on duty the day of the scan along with verification of the signed study consent. Pregnancy tests may be administered in the unit following specific guidelines, however the pregnancy screener must be completed electronically.**

All forms are located at <https://nyspi.org/mriforms>

Upon entry to the MRI Suite via the GROUP ENTRANCE, a table will be available with gloves and sealable plastic bags. 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 and prior clearance has been given by the MRI unit.** If additional family or staff are needed for this purpose, please clear and verify with the MRI unit prior to the scan.

**Study guidelines may allow for participant removal of the procedural mask during the scan*

Research staff are asked to please 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 and water bottles are allowed.

We strongly suggest advising participants to remove any metal/jewelry/etc ahead of time and to wear attire appropriate for scanning in order to minimize transition time.

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 should then be sealed. Participants will not be allowed to bring their own bags or purses to the MRI suite, however, small essentials (wallet, keys, phone, necessary personal items, 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 if needed, 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. The research staff member will stand the participant in view of the MRI operator.

If button box peripheral(s) are needed, the MRI operator will retrieve them for the research staff member after cleaning them with Sani-cloths once inside the scanner room and hand them off to the research staff member **Note - if placing peripherals or physiology - the research staff member may 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 by the research staff member. Any padding or material used will have been sanitized and disinfected.

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 prior to each scan session.

Unless needed for fMRI or physio monitoring, etc. The RA may optionally leave the suite during the scan temporarily after providing the operator with the best method of contact.

POST SCAN

After the completion of the scan, the MRI Operator and research staff member may don gloves if needed 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 disconnect any physio and peripherals, 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, if used, 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 should immediately exit the suite via the GROUP EXIT no later than 15 minutes after the end of their scan.

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 may change into clean scrubs and store their belongings. The MRI Operator will be screened at NYSPI entry point for temperature and will complete the staff questionnaire before arriving on site.

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.

Each day 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 - note: During phase I use of the mock scanner will be extremely restricted)

- 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, prevent overlap of participants, and allow for adequate air turnover and ventilation between subjects. **Groups will not be allowed to start early or run past their allotted time. If there is no group scheduled in the next slot, a group may run over time at the operator's discretion, however, they may be charged for excessive additional time.**
- **Normal cancellation fees will apply under the normal cancellation policy.** If a group accepts a slot assigned by the MRI unit, the normal 4 day cancellation window will be in effect.
- Before being allowed to scan, research staff will receive an outline review of all existing safety policies as well as an overview of the policies outlined in this manual to ensure there are no questions about procedure before beginning a study.
- **Testing time will be extremely limited.** The schedule is restricted to allow for adequate cleaning and disinfection, as well as to limit the number of people in the MRI suite. Due to these restrictions, non-test scan time will receive priority. Test slots may be preempted by paid scans when requested.
- **Access to the mock scanner is restricted.** Like the scans, you will not be booking this time yourself in Calpendo, Joe will be booking it. If you need access to the mock scanner, it will be in 30 minute increments max (or more depending on the following criteria), during either a) a period when no scan is happening, and it must end 20 minutes before the next scan begins so that there is zero participant overlap in the entry room, or b) during the middle of a scan happening in the real scanner, again ending at least 15 minutes before the real scan is finished so that there is zero participant overlap in the entry room.

A NOTE ABOUT SCHEDULING

Current scan slots on the calendar were given to groups that had IRB approval at the time the calendar was scheduled. As additional groups are granted approval, there may be a surplus demand for MRI slots. We encourage groups to be flexible with when they're willing to scan as we may have evening and weekend scan slots still available for groups willing to take advantage of those times.

With regards to prioritization and balancing the distribution of slots - consideration is given to whether or not a scan has clinical benefit to participants, whether or not scans for said studies are time-sensitive, other time-dependent factors in studies such as drug administration or treatment schedules, etc., total number of subjects needed within certain time frames, as well as the funding source of a study.

Cancelled scan slots are given similar priority, as well as additional consideration to groups that have lost time slots due to MRI technical downtime, or have willingly sacrificed time slots to help accommodate other studies.

In the recent past we've distributed late cancelled slots to groups that have reached out to us about them, and expressed a need for last minute scans in order to meet participant demand. If you'd like to be notified of these slots, please reach out to Joe. In addition, it's recommended that coordinators and RAs continue to monitor the calendar for slots that are cancelled both last minute and more than four days in advance. As always, we'll do our best to accommodate the varying needs of our study groups. Please don't hesitate to reach out if you have questions or concerns.

PREGNANCY TESTS

Pregnancy tests may be done in the MRI restroom. Please do not remove sample cups or other soiled materials from the restroom after use.

Test materials (including droppers, tests, sample cups, gloves, etc,) must be disposed of immediately after use in the red biohazard bin.

Under no circumstances should materials be left on surfaces (including any counter, the sink area, the floor, etc.) in the restroom nor should they be disposed of in the regular trash can.

Groups are asked to perform the test, when needed, within the 15 minute pre-scan window that they're allowed in the suite, and no earlier. We still need to allow for proper air exchange and disinfection before and after study groups.

Masks and any additional PPE required for these tests will need to be provided by the groups themselves. The MRI unit is making best efforts to keep a supply of gloves on hand, but due to severe availability and supply restrictions, we cannot currently guarantee adequate supply at all times for this purpose.

SOME HELPFUL INFO

Masks on at all times! If you or your subject enter the suite without a mask or with an improperly worn mask, you will be asked to leave. Most procedural masks have a metallic nose strip in them that we've found tends to be a little bit magnetic in many brands. During the scan itself (and per the IRB*), the subject may remove their mask for the scan, after being set up on the bed. If they prefer to be scanned mask-on (or if your protocol dictates such) we'll hand them a new, magnet friendly mask. RAs can use whatever mask they have - you may feel a tiny little tug near the bore if you have a surgical mask, but it's nothing substantial and not of any safety concern if you're not going into the actual scanner.

We will keep the bore fan on during the entire scan in order to move air through and out of the bore, and this may make the temperature feel a little cooler than normal when scanning. We'll do our best to keep plenty of blankets on hand, but our allocation from environmental services is divided amongst the patient wards as well, so we try to conserve where possible. That being said you may want to ask your participants to wear something with sleeves if they tend to run cold.

Please avoid last minute surprise metal, implants, etc., of any kind. We won't have the luxury of last minute approval so please make sure to have this information (and email pre-approval from Alayar if needed) ahead of time. You will still want the participant like normal, however this will be done in the "ON DECK" area which is indicated with fancy green tape on the floor. Please do not take the wand out of the "ON DECK AREA"

Button boxes - those will be kept in the magnet room. You'll still hook them up, but like the physiology, the tech will retrieve whichever one you need and hand it off. We're After the scan you'll hand it back to them for cleaning. For the headphones, if needed - pretty much the same as the button boxes and physiology. You'll still set it up, but the tech will retrieve the disposable ear-pieces for you.

If your participant needs corrective lenses, please know the prescription ahead of time. The tech will retrieve the frames and lenses for you and you'll hand it back to them for cleaning afterwards.

<https://nyspi.org/mriforms> has the online versions of the metal screener and pregnancy screener, which are on REDCap, and also fillable PDFs of the waivers you might need. There will be no more signing billing sheets, but Joe will send you a copy of the final billing sheet sometime after the scan. Please send PDFs of all forms to the tech doing the scan. It will either be matthew.riddle@nyspi.columbia.edu (sometimes), john.gray@nyspi.columbia.edu (weekdays), xiangling.mao@nyspi.columbia.edu (weekends) or frank.osorio@nyspi.columbia.edu (after 4pm on alternate weeks). You can also send a copy to joe.figliolia@nyspi.columbia.edu for posterity if you're not sure which tech is on, he loves email. PLEASE save or print a copy to keep for your group. We will delete these after verification. We also ask that you send a screenshot of the signature page of your consent form.

We will have sealable plastic bags for your participants to put anything they might bring with them that they haven't left upstairs as well as any items they may need to remove last minute. We ask that they don't bring bags of any kind.

Try to bring minimal things with you other than what's needed. Phones, a book, a laptop, a water bottle, those are all fine, and of course anything you need for the scan itself. Please don't bring bags or food containers. There is a line on both the desk and the floor, once again in that fancy green tape. This is the "social distance line" for the tech. We ask that no one comes any closer to the tech and/or console than this line during the scan.

The schedule is going to be pretty to-the-minute time wise. We aren't going to allow groups to run over time more than five minutes or so (and only if really necessary) because we need to use available time to clean/reset everything, let the air circulate out of the magnet room, and prevent any overlap between groups.

As always, please contact Matt and Joe if you have any questions.

ESTIMATED PPE REQUIREMENT

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

Number of Scans		
Daily Scans	4 x 5	20
Weekend Scans	4 x 2	8
Weekly		28
Total Scans Monthly		112
Supplies Per Scan		
Gloves (pairs)	RA, Operator	4
Procedural Masks	RA, Participant	2
Sanitizer	5mL pump/10 pumps	50mL
Sani-Cloths	Squeeze ball, Console, Bore, Coil, Cushions, Hard Surfaces, Chair arms, Door Handles, Restroom	13-15
Gown (as needed)	Subject	1
Clean Scrubs	Operator	1 Set (Daily)
N-95 Mask	Operator	1 (Daily)
Face Shields	Operator	1 (Daily)
Estimated Monthly Need		
Masks	50/Box	5 boxes (224 masks)
Gloves	50Pairs/Box	7 boxes (350 pairs, various sizes)
Sani-Cloth Wipes	80 Wipes/Bottle	16 bottles (1260 wipes)
Hand Sanitizer	2 pumps per use	4200mL
N-95 Masks	5 per operator	15 (3 Operators)
Face Shields	1 Shield	31 Shields

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.