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Effective Date: Aug 14, 2020			
Originator: Norman Butler, Shannon	Long,		
John Detre, MD, Kathleen Thomas			
Director, Research Operations:		Core Director:	

1.0 PURPOSE

This document details policies and procedures for reopening of the CAMRIS MRI Facility resources located at HUP in compliance with the COVID-19 Phase I Clinical Research Reentry Plan outlined by The Office of Clinical Research (OCR). Any question or issues should be directed to CAMRIS Core Administrator.

2.0 SCOPE

The policies and procedures in this document apply to all Researchers, Principal Investigators and research staff entering/operating in the CAMRIS Facilities in HUP. This includes Scanner Areas: HUP5, HUP6, Devon Center and PCAM MRI Scanners. The COVID-19 Research Resurgence Plan outlines policies/procedures surrounding but not limited to:

- 1. Social Distancing and wearing proper PPE
- 2. Research Subject management and logistics
- 3. Staggering of schedules
- 4. Workflow and Contact information
- 5. Cleaning/wipe down of contact surfaces
- 6. Clutter avoidance and removal

3.0 General Responsibilities

- 3.1 Social spacing distance of 6' or greater is to be maintained whenever possible.
- 3.2 Standard droplet protection masks are to be properly worn at all times while within the facility. Masking of subjects undergoing MRI will be mandatory in cases where subject can tolerate the mask (claustrophobia) and the imaging is not adversely affected (i.e. BOLD, ASL, and Thornhill imaging procedures).
 - 3.2.1 Note: although some subjects will not need to wear their mask during scanning. They must wear mask at all other times in the facility.
- 3.3 Only 3 people allowed in the MRI Suite at any given time (subject, MRI operator, and experimenter) and must maintain distance. Teams may switch personnel in rooms or use remote operation of instrumentation to avoid having more than 3 people at one time. One operator permitted at the scanner console.
- 3.4 If distancing is not practicable Study Team Members must use face shields in addition to masks.
- 3.5 Investigators are responsible for removing their ancillary equipment at the end of the scan session.
- 3.6 Time slots are to be respected. Over run or delay cannot cause issue with other scheduled sessions. Buffer time is not placed for long delays or over runs. If used as such they will be billed to the Investigative group.

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3.7 Caregivers are not permitted unless absolutely necessary. For exceptions, contact the CAMRIS Administrator.

Study Team Members (Principal Investigator, Research Coordinator, Research Assistant)

- 3.8 All personnel and Investigators will enter HUP through the White Building Entrance on Spruce Street as the Staff hospital triage entry point.
- 3.9 Subjects scheduled in Pennchart will enter HUP through the Main Entrance hospital triage entry points. These are located at the front entrances of both PCAM and HUP.
- 3.10 All personnel and Investigators must complete the EHRS "Penn COVID-19 Training for Lab Researchers" prior to entering facility.
- 3.11 All personnel and Investigators will be expected to follow all policies and procedures outlined in this document in addition to those already in place. Failure to do so may result in termination of your access.
- 3.12 Non-PennChart scheduled subjects must be COVID PRE-screened by the Investigative group 24 hours in advance of subject's arrival.
- 3.13 All personnel and Investigators will enter HUP through the White Building Entrance on Spruce Street as the Staff hospital triage entry point.
- 3.14 If a caregiver must accompany the subject, contact the CAMRIS Administrator.
- 3.15 Investigators need to provide current and viable contact information on calendar for updates about availability, delays and issues.
- 3.16 Investigators are responsible for maintaining the 1-hour buffer between studies.
- 3.17 MRI Coordinators that must violate the 6' distancing rule during the MRI session must wear droplet mask and face shield.
- 3.18 Investigators provide their personnel PPE.
- 3.19 NOTE: CAMRIS encourages all neurocognitive testing be done offsite from CAMRIS operations. For situations requiring an exception, you must gain CAMRIS pre-approval for use of this space.
- 3.20 Use of the HUP6 Exam Room MUST be prescheduled with Shannon Long or an MRI technologist.
- 3.21 Cleaning of HUP6 Exam Room is the responsibility of the MRI Technologist

MRI Technologists Responsibilities

- 3.22 MR Technologist will conduct final metal screening as well as a COVID-19 screening.
- 3.23 All MR Technologists will wear droplet mask and face shield when interacting with and positioning subjects in the scanner
- 3.24 MR Technologists will ensure all touch areas are disinfected with the appropriate solutions inside and outside the MRI area, waiting room area and inside the magnet bore.
- 3.25 MR Technologists will receive call from Coordinator & confirm subject/team member can proceed to the magnet area.
- 3.26 Delay information and updates must be relayed to the following scheduled Investigator
- 3.27 Cleaning of HUP6 Exam Room if utilized

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4.0 WORKFLOW For Scanner Areas: HUP5, HUP6, Devon Center and PCAM MRI

Pennchart Scheduled Subjects

- 4.1 Scheduling approval for studies using HUP5, Devon, PCAM to be sent to Shannon Long for approval until further notice.
- 4.2 Scheduling approval for studies using HUP6 to be sent to Margaret Ryan
- 4.3 PennCHART scheduled subjects will be COVID Pre-screened via HUP Radiology through Text and/or Phone 24 hours in advance of their scheduled time.
- 4.4 Study team to ensure MRI Metal Screening is completed prior to visit by using the MyPennMedicine online form or verbally upon subject arrival in Radiology check-in.
- 4.5 All outpatient subjects scheduled in Pennchart will enter HUP through the hospital triage entry points. These are located at the front entrances of both PCAM and HUP. Mask will be issued and required for entry to HUP and CAMRIS.
- 4.6 Subjects scheduled in PennChart Radiology must register at Radiology Check-In Area in Ground Dulles. Subject registration must be done to originate the visit into the Navicare system. No paperwork is to be used.

NON-Pennchart Scheduled Subjects

- 4.7 Scheduling approval for studies using HUP5, Devon, PCAM to be sent to Shannon Long for approval until self-serve open scheduling is reinstated (start date TBD)
- 4.8 Scheduling approval for studies using HUP6 to be sent to Margaret Ryan
- 4.9 Study team to complete MRI Metal Screening and COVID-19 screening within 24 hours of the scheduled appointment with subject via phone by using the CAMRIS web-based Metal/COVID Screening Form via link: https://redcap.med.upenn.edu/surveys/?s=JL48FJM894
- 4.10 CRC must escort subject to the facility after meeting them at HUP. The CRC must call the technologist when en-route to the facility (See REFERENCES section for scanner console telephone #s).
- 4.11 Upon arrival proceed directly to the scheduled scanner.
- 4.12 MR Tech will greet Coordinator and subject outside of the controlled space and appropriate discussion about preparation of subject for scan and screening confirmation will occur.

Note: Subjects who do not pass the COVID-19 screening will not be scheduled or scanned.

5.0 REFERENCES

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Office of Human Research (OCR) Document titled PSOM Phased Clinical Research Reentry Program May 8 2020.docx

Scanner Console tel#s HUP5—215-349-5298 HUP6—215-662-3057 Devon MRD1—349-5596 PCAM—please call HUP6 or HUP5 to speak to CAMRIS Research Technologist

6.0 ATTACHMENTS

PSOM Phased Clinical Research Reentry Program May 8 2020.docx