Introduction to COVID-19 Revised SOPs and Phase I Resupmtion of TECHDEV Scanner Operation (CAMRIS)

In response to the COVID crisis and PSOM current Phase 1 reopening of limited research, CAMRIS will be putting in place the following common procedures/policies in all CAMRIS Imaging Facilities regarding Technical Development Imaging (TechDev):

TechDev access is limited to those that have undergone successful training in the safety and use of the MRI systems and been given the standing of "TechDev Users". This includes training on system cleaning procedures for the MRI systems. This must be done prior to any TechDev use.

Types of TechDev operation (scanning) are:

1- Operator only "Remotely"– TechDev user works remotely scanner during the session.
2- Operator only scanning "Locally"– TechDev user scans specimens acquired from a lab
3- Operator scans TechDev Subject – TechDev operator scanning session using a TechDev consented volunteer

All "Remote" access is approved through NNC. Please contact Dr. Detre and/or Dr. Tisdall for this approval. These are scheduled access times and must be coordinated with CAMRIS. No remote operation should overlap or cause issue with local system operations. All system failures and problems must be reported and resolved. Remote User must be able to respond to issue they have created.

All "Local" TechDev allows for only one person to be present. No Exceptions.

Type 3 must be approved by Dr. Larry Dougherty and Dr. Dave Mankoff. No type 3 operation can be performed without this approval. Email Shannon Long to initiate the review process Shannon.long@pennmedicine.upenn.edu.

These Policies and procedures relating to types 2,3:

1. COVID Screening
2. Occupancy Level
3. Social Distancing
4. PPE during
5. Arrival and work flow
6. Cleaning procedures after session

1. COVID screening will be part of Type 2,3 of TechDev:
    a) All System Operators will have reviewed and understood the "Penn COVID-19 Training Module" offered through Knowledgelink
    b) System Operators imaging on University personnel must self temp check and be symptom-free before arrival.
    c) TechDev subjects (Type 3) are screened with COVID screening procedure as outlined by HUP within 24 hours of their arrival. This screening occurs remotely (see SOP for details) to reduce density in the scanner facility.
    d) Upon arrival all must wear droplet mask at all times. NO EXCEPTIONS.
    e) Type 3 Operator must wear mask and shield when working with subject.

2. Occupancy totals for the facilities will be limited to or below the 20% occupancy level ordered by the University. TechDev will be limited in the number of people involved in the sessions. Type 2 is “ONE” person. Type 3 is “2 people”. Additional personnel are not to be added to this scenario.

3. Social Distancing of the suggested 6’ will be maintained whenever practicable. In Type 3 sessions the operator will wear both mask and Face shield during the session. The subject must wear droplet mask entire time, including time in scanner.

4. Workflow must be designed to limit time spent in the imaging facility. Cleaning procedures must be reviewed and followed.

    f) PPE will be needed and is provided by the TechDev User. All persons involved will wear a droplet mask the entire time they are in CAMRIS Facility. This is for limiting droplet contamination of contact surfaces. Gloves should be used during the session and contact with shared surfaces and equipment. ***No Mask-No Scan.***

5. Preparation specific to having an MRI done should in general be taken care of BEFORE operator arrives to allow for an efficient running of the session. ALL of these should be taken care of PRIOR to arrival in department by the Investigative team:
    a) Pre-check on the scanner being open and available.
    b) Preparation of all phantoms and specimens. Time is not to be spent in CAMRIS facility prepping these items.
    c) Coils and software prepared, set-up and ready.
    d) Drop off and pick up of items necessary for session should take place in facility only if absolutely necessary.

6. Arrival and Workflow – All Operators will spend minimal time in the facility. If the design of the experiment (session) is scanning remotely, a designated individual must be available to assist with set-up and issues that might arise. This individual must be able to physically come to the scanner within a reasonable time frame.

7. Post session cleaning and buffer time – each scanner is equipped with disinfectant pads that will be used by the operator to clean all contact surfaces at the end of each imaging session. The MRI Bore in its entirety will be wiped down as will all peripheral equipment used for the study. A 1-hour delay will follow the session unless otherwise agreed upon by CAMRIS facility. Surfaces outside of the MRI room involved in scanning must be wiped down prior to the next session. This includes all shared instruments, keyboards, and desk/counter tops.

How to Gain Approval to scan for Techdev during Phase I Reopening

With the phased return to clinical research, the TECHDEV protocol will be available for initial human testing of devices or sequences. Research will be prioritized into Categories described in the guidelines set forth by the Office of Clinical Research

(https://www.med.upenn.edu/ocrobjects/secure//News/PSOM_Phased_Clinical_Research_Reentry_Plan_May_08_2020.pdf).

Prior to starting your research, please send the following information to Shannon Long at Shannon.long@pennmedicine.upenn.edu

1. PI:
2. Names of personnel performing research
3 Study title:
4. Category of your research: A, B, C
5. Description of Research and Rationale for Category A,B, or C.
6. Is MRI tech needed or Level II tech plan on running scan (if so, please name)
7. Are subjects already consented through TECHDEV protocol with Shannon?

CAMRIS will review each request. Until further notice, you must obtain approval to scan before blocking time on the schedule.

In addition, please reduce the pool of approved volunteers you will scan. Only those volunteers directly involved in the development of the device/sequence should be used for human testing.