Returning to Research Amidst the Pandemic: the UW Experience
> Shut down most lab activities ~ 2\textsuperscript{nd} week of March
> Gradually resuming again in June, in phases
> Strict procedures in place for return to lab activities
  1. low risk of complications should the participant contract COVID-19*
  2. well-ventilated spaces with capability to physical distance
  3. minimal close direct contact

\textit{e.g} SCI 2.4x greater risk of death with COVID-19
University of Washington’s Rehabilitation Medicine COVID-19 Research Safety Plan: Brown Lab

1. List of personnel who may work onsite within the next 3 months and subsequently will be covered by this safety plan:
   - Mary Beth Brown – Principal Investigator
   - SiWei Luo – Postdoctoral Scholar / Lab Manager
   - Morgan Kelly – Study Coordinator
   - Haley Seelow – DPT Student
   - Mesay Gashun – DPT Student
   - Julia Guilliams – DPT Student
   - Hunter Furutani – Undergraduate research assistant

2. Specific physical location where the onsite research activities covered by this plan will take place, including room numbers:
   - Health Sciences BB-026
   - Fred Hutch Prevention Center in South Lake Union
   - Animal Research and Care Facility - Comparative Medicine Vivarium
   - SLU1 Broman - Comparative Medicine Vivarium

3. COVID-19 Supervisor:
   - Mary Beth Brown

Below are the roles and responsibilities of COVID-19 Supervisor as provided by UW Medicine:

- Develop and ensure site-specific COVID-19 Prevention Plans, including social and physical distancing requirements, are adhered to.
- Ensure that everyone working onsite has been trained in the site-specific COVID-19 prevention plan, and maintain a log that records the date that the training was completed for each individual.
- Keep unit and/or site-specific plans current with changes to COVID-19 guidelines, regulations and University policies.
- Ensure the implementation of approved attestation mechanisms for all individuals (e.g., Workday, Catalyze) or other method for individuals without a profile in Workday. Log books or other appropriate methods for visitors, etc.) coming to the worksite. Ensure review of daily attestations for those who come to the worksite by the appropriate supervisor.
- Be available (e.g., on site or by cellphone) during site activities to monitor compliance and answer questions and concerns as needed.
- Report safety concerns to a supervisor (e.g., PI, department administrator) or directly to EHS & I according to unit- and site-specific plans.
- Work with other groups/personnel outside the scope of this plan but in close physical proximity to ensure physical distancing and cleaning/disinfecting procedures are maintained in the worksite.

4. All personnel will be trained on specific details of the safety plan before they begin working onsite:
Impact of COVID-19 on Clinical Research Activities: University of Pittsburgh Physical Therapy Experience

James Irrgang PT PhD FAPTA
Professor & Chair
Department of Physical Therapy

Research Intensive Programs in Physical Therapy

July 22, 2020
Essential vs. Non-Essential Research

Tier 1 – High Direct Benefit to Participants or High Public Health Priority
• Would result in serious or immediate harm to study participants if research stopped
• Research can continue if it can be done safely for all involved, however recruitment of new subjects must stop unless there is compelling reason to continue recruitment

Tier 2 – Moderate Direct Benefit to Research Participants
• If research stopped, it may pose risk to research participant
• Research can continue but must cease in-person interactions, however PIs can petition IRB if there is compelling reason to continue in-person interactions

Tier 3 – Low Benefit to Research Participants & Other Impacts of Research
• Delays to starting or pausing research does not substantially impact research objectives
• No further enrollment of new participants requiring face to face interactions or continue face to face visits
Initial Experience for PT Research

• All in-person research activities involving human subjects terminated March 20, 2020
• Resulted in closing of Physical Therapy-Clinical & Translational Research Center (PT-CTRC)
• Suspension of new subject recruitment and in-person research interventions & follow-up
• All research personnel transitioned to working from home (remote data collection, planning, writing, remote meetings, data analyses etc.)
Initial Experience for PT Research

• Outpatient clinical visits & surgery ramped down - converted to telemedicine visits
  • Clinical visits & “non-essential” surgery gradually resumed late April but not able to support clinical research efforts

• IRB exception submitted to permit:
  • Remote research interventions & follow-up
  • Allow research personnel to contact subjects via phone to obtain certain data (complications, medication changes, AEs, home exercise logs)
  • Out of window clinical & research visits
Resumption of Clinical Research Activities

Procedures for Research Restart Plan Announced June 3, 2020
(Coincided with Region Moving to Green Phase)
Research Restart Plan

Assumptions:

• Safety of study participants, investigators, research staff, University community & region is of paramount importance
• Planning grounded in science & guidance from CDC & UPMC Wolff Center for Quality, Safety & Innovation
• Clinical research is an essential University function
• Restart of research will use a phased approach
• All work that can be performed remotely should continue to be performed remotely
• Must be prepared for setbacks & ability to reduce research if necessary
Research Restart Plan

Process:

• Principal Investigator/Lab Director created restart plan that addressed mitigation of COVID-19 transmission, orderly restart of research & procedures to ramp-down research if it becomes necessary
  • Template provided by University
• Plan reviewed and approved at Departmental & School level
• Prior to approval to restart research, research space also had to be reconfigured, inspected & approved:
  • Furniture & equipment re-arranged for social distancing
  • PPE & disinfecting supplies on hand
  • Signage posted to promote social distancing, use of face masks, hand cleaning, disinfecting equipment & surfaces after use/touching
Research Restart Plan

Components of Plan:

• COVID-19 screening of participants within 24 hours of scheduled research visit and again at arrival:
  • COVID-related symptoms
  • Exposure to individual with known or suspected travel
  • Recent travel to high-risk areas or travel by air

• Social distancing
  • Re-organization of equipment & space as necessary
  • Restricted scheduling to avoid wait times & limit number of subjects at any one time
Research Restart Plan

Components of Plan:

• Personal protection equipment (PPE) – followed CDC & Wolff Center guidelines:
  • Minimum of surgical face mask worn by research staff & subject at all times
  • Eye protection if within 6 feet or direct contact with subject
  • N95 face masks if aerosolizing procedure (NOTE: this was deemed to include moderate aerobic exercise such as walking on treadmill/riding ergometer)
• Frequent hand cleaning including before and after contact with subject
• Cleaning & disinfecting of equipment and surfaces before and after each use (including keyboards & tablet computers)
Research Restart Plan

Components of Plan:

• Education of all research staff – included training specified by:
  • University
  • UPMC Wolff Center
  • Clinic/lab specific

• Daily attestations completed by research staff:
  • COVID screening questions
  • Time in/out
  • Individuals in which there was contact for > 5 minutes within 6 ft

• Clinic log of all personnel & subjects including times in & out

Need to Have Information Necessary for Contact Tracing
Research Restart Plan

Components of Plan:

- Work schedule for research staff modified to include only those necessary to be present for in-person research activities - considered:
  - Social distancing parameters
  - Number & qualifications of staff needed
  - Age & health of research staff

- Patient facing materials (letter) generated & distributed:
  - Welcome
  - Screening procedures
  - Arrival procedures
Completion of IRB Survey for Each Study Was Required Prior to Resuming Research Activities

- Why can’t the enrollment be postponed until restrictions are lifted?
- What is the harm to subject or value of data lost if in-person visits cease or are delayed until restrictions are lifted? (Tier 2 and 3)
- What measures are being taken to minimize in-person visits, e.g. visits may be done remotely or coincide with clinical visits?

Generally IRB Modification Was Not Required
Research Restart Within UPMC Clinics

• Study-related activities include:
  • Participant screening, recruitment & consent
  • Standard of care intervention & clinical follow-up
  • Research follow-up activities

• Follow UPMC clinical guidelines & practices for mitigation of COVID-19

• Limited clinical research assistant in clinic for recruitment & research follow-up
Effects of COVID-19 on Tenure-Stream Faculty

One-Year Temporary Type E Transfer Out of Tenure Stream Given to All Tenure-Stream Faculty Upon Request
What’s Next?

Pitt Resilience Plan

- Most instruction is in person, except large lectures
- Housing open with virus mitigation and isolation interventions in place
- Shared spaces open
- Gatherings capped at 250 people

- Work from home encouraged wherever possible
- Those who need to support permitted activities allowed on campus

- Research staff on campus based on Principal Investigator determination

GUARDED RISK

- Most activities are in person, with virtual options and limited restriction
- Instruction primarily virtual; some in-person learning occurring
- Housing open with virus mitigation and isolation interventions in place
- Some shared spaces open
- Gatherings capped at 25 people

- Work from home encouraged wherever possible
- Those who need to support permitted activities allowed on campus

- Virtual work encouraged for research personnel; some permitted on campus

ELEVATED RISK

- Some activities are in person, but most are virtual
- Instruction nearly all virtual, except select clinicals and labs
- Housing open with virus mitigation and isolation interventions in place
- Some shared spaces open to support on-campus students and staff
- Campus life activities not permitted

- Work from home encouraged wherever possible
- Those who need to support permitted activities allowed on campus

- Research as permitted by senior leadership

HIGH RISK

- Pitt is open, but activities are heavily restricted
- Face coverings required on campus. Physical distancing is necessary, with a minimum of six feet between you and others when possible.

“Im doing my part to keep the Pitt community safe.”
coronavirus.pitt.edu
Never Ever Stop Reinventing
Progress Is Always Progress
Forge Ahead!

H2P – Pitt PT!