Returning to Research Amidst the Pandemic: the UW Experience

BE BOUNDLESS

UW Medicine

- Shut down most lab activities ~ 2nd 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

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 <u>may</u> 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 Sizelove – DPT Student
   Missy Garvin – 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-826
   Fred Hutch Prevention Center in South Lake Union
   Animal Research and Care Facility- Comparative Medicine Vivarium
   SLU1 Brotman- 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, Catalyst 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 EH&S 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 workspace.

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

University of Pittsburgh | Department of Physical Therapy
School of Health and Rehabilitation Sciences

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

University of Pittsburgh | Department of Physical Therapy
School of Health and Rehabilitation Sciences

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)

University of Pittsburgh
Department of Physical Therapy
School of Health and Rehabilitation Sciences

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

University of Pittsburgh | Department of Physical Therapy
School of Health and Rehabilitation Sciences

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

University of Pittsburgh | Department of Physical Therapy
School of Health and Rehabilitation Sciences

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

University of Pittsburgh | Department of Physical Therapy
School of Health and Rehabilitation Sciences

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

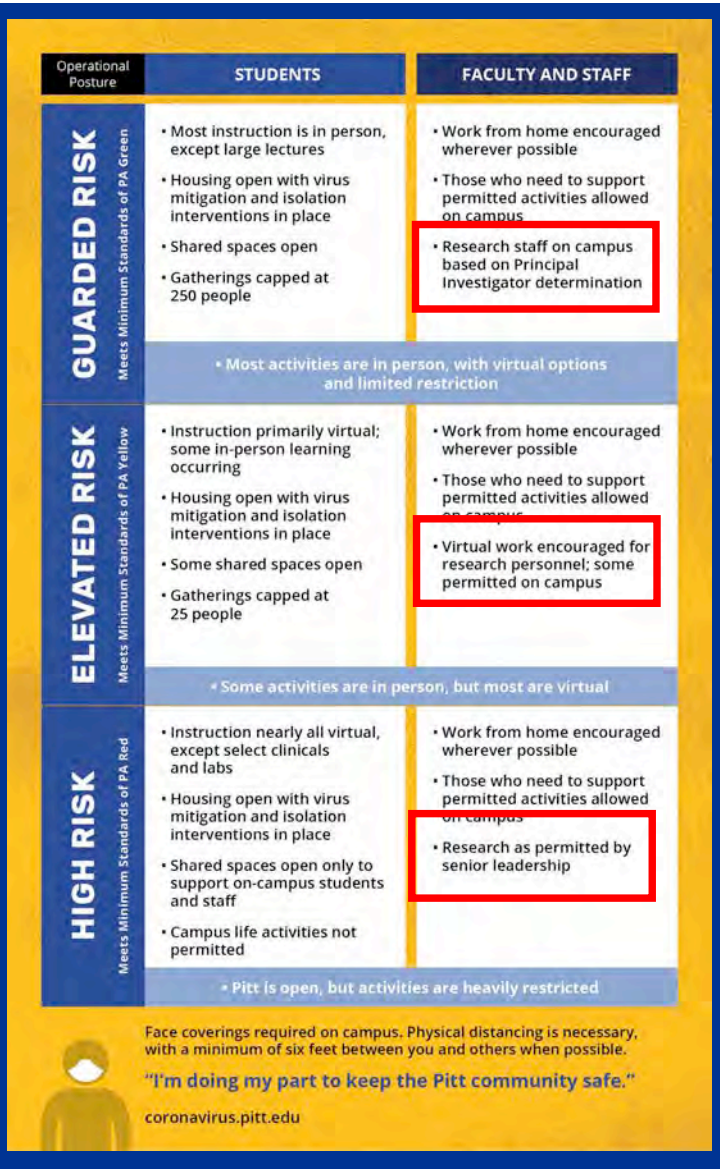
Effects of COVID-19 on Tenure-Stream Faculty

One-Year Temporary Type E Transfer Out of Tenure Stream Given to All Tenure-Stream Faculty Upon Request

University of Pittsburgh
Department of Physical Therapy
School of Health and Rehabilitation Sciences

What's Next?

Pitt Resilience Plan



University of Pittsburgh | Department of Physical Therapy
School of Health and Rehabilitation Sciences


Never Ever Stop Reinventing
Progress Is Always Progress
Forge Ahead!
H2P – Pitt PT!