



**UNIVERSITY OF PITTSBURGH
SCHOOL OF MEDICINE AND UPMC
CLINICAL TRIAL MONITORING GUIDANCE**

AUGUST 5, 2020

Clinical Trial Study Monitoring Visits during the COVID-19 pandemic must be modified based on the current Pitt Operating Posture (see below). The current posture can be found at <https://www.coronavirus.pitt.edu/operational-postures>.

Pitt Operating Postures:

High Risk Posture	Elevated Risk Posture	Guarded Risk Posture
Meets the minimum standards of Pennsylvania’s red phase. The University is open, but activity is heavily restricted.	Meets the minimum standards of Pennsylvania’s yellow phase. Campus activities are at a minimal level, prioritizing activities that have high value but lower risk.	Meets the minimum standards of Pennsylvania’s green phase. Fewer restrictions are in place, while mitigation measures remain. Activities will account for chronic risk of operating during a pandemic while continuing to prioritize health and safety.

Study Monitoring Visit Activities:

Elevated and High Risk Postures:

1. Default position: monitoring visits are done remotely or are rescheduled
2. If visits must be done in person, then all Pitt and UPMC COVID-19 guidelines must be followed, as applicable (<https://www.policy.pitt.edu/university-policies-and-procedures/covid-19-standards-and-guidelines>). The University’s safe mobility standards and guidelines apply to study monitors (https://www.policy.pitt.edu/sites/default/files/covid/Safe%20Mobility.071320_0.pdf).
3. All monitoring visits conducted in UPMC facilities must follow UPMC facility access guidance. Monitor access to UPMC EHR data must follow UPMC guidance (contact OSPARS@upmc.edu for details)

Guarded Risk Posture:

1. Default position: onsite monitoring visits are permitted
2. All Pitt and UPMC COVID-19 guidelines must be followed, as applicable (<https://www.policy.pitt.edu/university-policies-and-procedures/covid-19-standards-and-guidelines>). The University’s safe mobility standards and guidelines apply to study monitors (https://www.policy.pitt.edu/sites/default/files/covid/Safe%20Mobility.071320_0.pdf).
3. All monitoring visits conducted in UPMC facilities must follow UPMC facility access guidance. Monitor access to UPMC EHR data must follow UPMC guidance (contact OSPARS@upmc.edu for details)

Questions about study monitoring visits can be sent to restart.clinicalresearch@pitt.edu