

Clinical research activity has been limited to protect the safety of research participants and NJH research team members since March 16, 2020 when NJH released guidance in response to COVID-19. With the initial peak of COVID-19 behind us, NJH, Sponsors, the NIH and other sites are implementing a path forward for clinical research.

NJH will implement a multi-stage approach to re-start current clinical trials and to prepare for new ones. This approach will be a risk-based one as we continue placing an emphasis on participant and NJH staff safety. Clinical trial activity will follow these stages:

	Allowable Clinical Trial Activity	Allowable Procedures for Research	Projected Timeline
Stage I	<ul style="list-style-type: none"> • Current state: <ul style="list-style-type: none"> ○ Already Active Interventional Studies: In person visits (per participant choice) for currently enrolled ○ Already Active Observational Studies: In person visits if participant is at NJH for clinic visit ○ Continue with remote visit options per Sponsor/Participant desires • Already Active Observational Studies: Open to new enrollment and in person visits of Local Participants Only 	<ul style="list-style-type: none"> • No aerosol generating procedures • Limit use of PPE • Utilized data from spirometry performed for clinical purposes (must have negative PCR, must be done in PPU) 	Mid-Late May 2020
Stage II	<ul style="list-style-type: none"> • Already Active Interventional Studies: Re-start new enrollment to Local Participants Only • Already Active Interventional Studies: Re-start in person visits with Out-of-State Participants 	<ul style="list-style-type: none"> • Aerosol generating procedures (e.g. nebulization, induced sputum, MBW, spirometry, NPD, nasal scraping, exhaled NO), negative pressure room meeting institutional guided minimum air exchange requirements and full PPE required 	June 2020 <i>Sponsor on-site visits allowed</i>
Stage III	<ul style="list-style-type: none"> • Observational Studies: All activity and enrollment open • New studies pending activation are open to enrollment 	<ul style="list-style-type: none"> • <i>At this stage, we must have the capability to conduct all protocol required procedures and insure that available PPE presents no limitations to procedure conduct</i> • Bronchoscopy and Laryngoscopy 	July 2020
Stage IV	<ul style="list-style-type: none"> • All Studies, Out-of-State participants able to travel to site 		July/August 2020

Research activities will follow Institutional guidance (i.e. PPE requirements) and be informed by decisions made by the Phoenix Committee for specific procedures (i.e. aerosol generating procedures).

Timeline may be adjusted for subject and staff safety based on successful transition (no COVID related adverse outcomes in research subjects, or local outbreaks of disease) through stages and PPE availability.

Participants will be pre-screened via telephone utilizing the NJH COVID questionnaire on the day prior to the visit. Masked participants will be allowed to be accompanied by one masked visitor. The Goodman floors will remain badge-access for the foreseeable future. Therefore, upon arrival, the participant (and visitor) will be escorted by the research coordinator directly to a CRU/CTRC room to undergo temperature screening. For participants with temperature >100° F, the visit will be terminated, and the PI and Nursing Supervisor will be contacted to determine participant disposition.

Individual study appeals can be sent for review to Dr. Downey's office.