**Clinical Research Ramp-up General Guidelines**

- Primary goal is to resume clinical research safely for research study participants, caretakers, and staff
- All work that can take place remotely will continue to take place remotely
- Ramp-up of clinical research staffing parallels **wet bench staffing ramp-up**
- Only clinical research encounters supportable by staffing level restrictions can occur
  - Not all research encounters will be able to occur, and not all studies can accrue
- Only clinical research encounters supportable by available clinical services can occur
  - Clinical services are not at 100% capacity, and this will limit study accrual
- Current Covid-19 requirements for patient clinical visits also apply to all encounters with research study participants and caretakers, including pre-screening, PPE use, and physical distancing
- Principal Investigators are responsible for:
  - Applying Clinical Research Task Force guidelines to each research study and encounter with study participants and caretakers
  - Ensuring adequate research staffing and clinical services are available to meet protocol defined observations
  - Ensuring that all research study staff are trained in PPE use
  - Ensuring research study participants and caretakers are comfortable in resuming in-person research
- Clinical Research Task Force Guidelines will soon be available and updated as necessary, in response to the evolution of the pandemic and experiences of the initial research activities ramp-up

**Timeline as of May 18, 2020, for Clinical Research Ramp-up**

- Category I: Currently permitted
  - Essential clinical trials, SARS-CoV-2 clinical research, fully remote clinical studies
Clinical Research Ramp-up General Guidelines

- Category II: Permitted May 26, 2020 for existing clinical studies
  - In-person research visit CONCURRENT with clinical visit
  - Research/biobank samples may be collected, provided the in-person research visit is concurrent with clinical visit AND the laboratory team can accept the research sample
- Category III: Permitted upon Philadelphia transition to Yellow Zone for in-person research visits NOT concurrent with a clinical visit for clinical studies in an affected population
  - Category IIIA: Concurrent with Yellow Zone transition: Previously scheduled in-person research visits canceled due to COVID-19 study restrictions may be rescheduled
  - Category IIIB: To be decided with target of 14-21 days post Yellow Zone transition: New in-person research visits
- Category IV: To be decided depending on state of pandemic and safe ramp-up success through categories I, II, and III
  - Clinical research visits involving healthy volunteers as study participants