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 July 24, 2020, for Clinical Research Ramp-up

- Category I: Currently permitted
    - Essential clinical trials, SARS-CoV-2 clinical research, fully remote clinical studies

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- Category II: Currently permitted
    - 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: Currently permitted
    - Category IIIA: Previously scheduled in-person research visits in affected populations canceled due to COVID-19 study restrictions may be rescheduled
    - Category IIIB: New in-person research visits in affected populations
- Category IV: Permitted July 27, 2020
    - Clinical research visits involving healthy volunteers as study participants