Reopening Clinical Research at UofL

- Human Subjects Research may proceed only to the extent that it can be performed safely and in alignment with government, university, sponsor, and facility guidelines
- UofL reopening guidelines apply to all clinical studies, including those that were approved in mid-March to continue during the COVID-19 ramp down
- Tiered approach to reopening halted clinical research:
- Tier 1 (June 1): Existing interventional studies may resume with currently enrolled participants
- Tier 2 (Target June 15): Existing studies may enroll new participants and new interventional studies may begin
- Tier 3 (Target June 29): All other studies may resume (biorepository specimen collection, observation studies, etc.)
- Investigators wishing to conduct / reinitiate studies prior to this timeline can request approval via the exception process established during the COVID-19 ramp down

Reopening Clinical Research at UofL

- All personnel must complete and submit the Employee Self-Assessment Requirements and Attestation prior to returning to campus.
- Recommend continuing with remote visits as permitted by study protocol.
- Screening and requirements for research office visits:

  Screen for symptoms, limit caregivers, required masking, eliminate traditional waiting areas, physical distancing, limit exposure.

- Personal Protective Equipment (PPE) use:

  Industry sponsors must provide non-standard PPE when required

  Investigator initiated studies must obtain approval for non-standard PPE use from the facility research office.

- In person sponsor visits may not occur at this time.
- https://louisville.edu/research/covid19resources/resources