Resuming "in-person" human subjects research at LSU: A guide for Researchers 8/17/2020

Rationale: COVID-19 has dramatically changed the potential risk individuals encounter in their daily life. Resuming "in person" human subjects research does not inherently exceed this "minimal risk" so long as

- a) Researchers and subjects are aware of these potential risks.
- b) Appropriate precautions are taken to minimize these risks to research subjects

COVID-19 related risks: There are two chief risks with resuming "in person" research. First involves potential exposure to the COVID-19 virus. In order to mitigate this, researchers must adhere to all relevant CDC, Louisiana Department of Health and LSU guidelines. At present, this includes physical distancing, wearing of face masks, and disinfecting of relevant surfaces. These guidelines will likely evolve over time, and researchers should be aware of changes and update their protocols accordingly.

A second source of risk stems from mitigation strategies aimed at curbing the spread of COVID-19. At present, LSU researchers, students employees and visitors should comply with daily symptom checklists, reporting of positive test results, contact tracing, and isolation/quarantine guidelines. If study personnel, for example, tests positive for COVID-19, immediate isolation may be mandated for that individual and anyone they were in close contact with. Without appropriate safeguards, a single positive case can lead to isolation/quarantine for an entire network of research assistants, subjects, peers, friends and family.

IRB Protocols: If you are considering "in-person" human subjects research while under threat of COVID-19, you will be asked to address these potential risks. This can be provided in modification to an existing protocol or in a new IRB application. As of July 1, 2020, the IRB is using a new submission system. Information about this can be found here:

https://www.lsu.edu/research/resources_for_faculty/research_compliance/irb.php

In your documents, please:

- Provide a rationale for why "in-person" contact at the present time is vital to your research question, methods, and/or timeline.
- Provide a plan for complying with general health and safety guidelines. This plan should include relevant prescreening, disinfecting, distancing, isolation/quarantine and other activities, and should include a plan for monitoring appropriate regulatory agencies for updates. The LSU Emergency Operations Center website is a useful link: https://www.lsu.edu/oep/eoc/index.php
- Provide a plan for ensuring potential subjects are aware of risks (e.g., isolation/quarantine guidelines). This can be provided in a supplemental handout. Changes to the consent are typically not necessary.
- Note the potential screening, involvement and need for additional risk mitigation strategies for "high-risk" individuals (as defined by LSU, LA DHH, and CDC).

IMPORTANT NOTE: Additional administrative approval may be needed for you to resume in-person research. At present, research occurring on LSU campus requires relevant departmental chair and dean approval.

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