Dear Sponsor:

The COVID-19 crisis and requirement for social distancing, concern about spread in the healthcare environment, and concern in protecting our personnel and, most importantly, our patient/subjects have caused us to adopt procedures in line with guidance from the FDA and in line with the procedures adopted by the Johns Hopkins Institute for Clinical and Translational Research (https://ictr.johnshopkins.edu/coronavirus/johns-hopkins-human-subjects-research-moves-to-phase-3-of-the-contingency-plan-march-22/). Ochsner Health has classified its clinical trials by the Tier 1, 2, and 3 criteria laid out in the Hopkins document (see appendix to this letter).

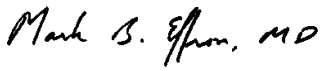
Until further notice, Ochsner Health is implementing the following policies:

1. Tier 1 studies related to COVID-19 will be a priority focus and will run as usual on an accelerated timeline.
2. Tier 1 oncology studies that provide a therapeutic anti-cancer agent will still continue to enroll.
3. All other Tier 1 studies will suspend new enrollments unless the principal investigator (PI) petitions Ochsner Research Administration and demonstrates a compelling need to continue new enrollments.
4. *In person* study visits for Tier 2 studies are suspended, unless the PI petitions Ochsner Research Administration and demonstrates a compelling need to continue.
5. *In person* study visits for Tier 3 studies are suspended.
6. If study visits can occur remotely (by telephone or computer-based visits), study visits will continue as scheduled. This difference in obtaining follow-up information will be documented in the visit notes.
7. If possible, study drug will be mailed to patients at appropriate times where self-administration is the typical form of administration of the drug. This needs to be done with the consent of the sponsor.
8. No new Tier 2 or Tier 3 studies will be initiated if in person visits are required. If enrollment, consent, dispensing of study drug (if needed), and follow-up for a new study can all be accomplished by remote means, then the new trial will be allowed to open.

9. While the Office of Sponsored Programs will prioritize getting COVID-19 studies started, work will continue on other studies to ensure they are ready for implementation once the pandemic crisis is under control.

In these trying times, the most important action we can take as a research institution is to protect the health and safety of our patients/subjects and healthcare personnel involved in our clinical research. If you have any questions or concerns, please let me know.

Sincerely,



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APPENDIX:

Tier 1 – High Direct Benefit to Research Participants

All protocols involving COVID 19 and protocols in which serious or immediate harm could be caused to the research participants if stopped.

For example:

- Research protocols involving treatments for acute, life threatening health conditions (e.g. some treatment trials for cancers)
- Protocols where stopping the intervention (e.g., some investigational drugs or vaccines or preventative drug regimens) could be harmful

Tier 2 – Moderate Direct Benefit to Research Participants

Protocols which, if stopped, may pose a risk to the research participant.

For example:

- Protocols in which research participants are receiving interventions or clinical care that is very interrelated to their research participation (e.g., test results coming back that might have clinical implications for their care)
- Some protocols evaluating treatments for chronic conditions (e.g., asthma, hypertension, depression, etc.).
- Protocols involving assessment of the safety or efficacy of an intervention in which, if stopped, the potential societal benefit of the science would be significantly and adversely impacted, for example where a research assessment (blood collection or imaging study) is only valuable if collected at a very specific time. This must be measured against the risk to participants, including the risk of exposure of COVID-19.

Tier 3 – Low Direct Benefit to Research Participants

- Cohort and natural history studies where delays in data collection have limited impact on scientific objectives
- Protocols in which delays to starting or pausing of research does not substantively impact on research objectives of the research protocol
- Protocols in which risks to research participants are higher (e.g., potentially exposing elderly vulnerable individuals to COVID) and benefits of the study to the participants remain minimal
- Research with healthy volunteers
- Any minimal risk studies that require research subjects to travel, that involve undergraduate students, or that are in a community setting and require direct interaction with researchers