RUTH O'HARA, PhD
Senior Associate Dean for Research
Professor, Department of Psychiatry and Behavioral Sciences
Director, Sierra-Pacific MIRECC Translational Core

Dear Faculty, Staff, Postdocs and Students,

Here is guidance regarding the conduct of Clinical Trials and Clinical Research, which we have developed with the Vice Provost and Dean of Research, Dr. Kathryn Moler.

The County Order issued on March 16th, curtailing activities for the next three weeks does not prevent clinical trials and clinical research from going forward. Below are the restrictions on such trials and research that we are putting in place.

All non-essential, in-person patient or human subject visits should be postponed until further notice in order to contain the spread of COVID-19. Research that can be conducted virtually can continue.

Ongoing treatment studies that provide essential therapeutic support for our patients, or where cessation of the treatment could negatively impact patient outcomes, can continue with in-person visits. Clinical research that obtains critical, in-person observations or laboratory measures on vulnerable patients or populations where not obtaining these observations could negatively impact patient safety, can continue as usual with in-person visits. Any non-essential visits or follow-up visits for these essential treatment trials or clinical observational studies should be postponed or conducted virtually where possible. Determination of which treatment trials or clinical observation studies can continue as usual with in-person visits should be made in consultation with your Department Chair or designee, or your Institute Director. All necessary safety precautions as outlined on the EH&S website should be taken for all in-person visits.

No new treatment studies or clinical observation studies should be initiated until further notice, as we may have limited clinical personnel to conduct such activities. If you believe a new trial is essential, e.g. for COVID-19, please contact your Departmental Chair or your Institute Director for their adjudication.

You will need to report any modifications to your Clinical Trials or Clinical Research (e.g. moving to virtual visits) to the IRB. Understanding that resources must be prioritized to contact and protect your human subjects, please file a revision to your eProtocol when you can, to confirm any changes. The IRB is available to assist you with your protocol revisions.

Modifications to your Clinical Trials and Clinical Research may also need to be reported to the study sponsor and require modification to the budget and contract. Please coordinate these activities through RMG.

While no new treatment studies or clinical observation studies should be initiated, if they are already under negotiation, RMG can continue to work on the budget and the contract with sponsors. The PI and RMG should coordinate with the sponsor on the start date for the study.

Where additional guidance is needed, please do not hesitate to contact the Senior Associate Dean for Research in the School of Medicine, Ruth O'Hara, Ph.D., at pooneh.fouladi@stanford.edu

Many thanks,

Ruth O'Hara, Ph.D

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