**Subject:** Updated guidance regarding clinical trials and clinical research

*Sent on behalf of Ruth O'Hara, Senior Associate Dean for Research*

Dear Chairs and Institute Directors:

As outlined below, we are updating our previous guidance regarding the conduct of Clinical Trials and Clinical Research. Please inform your faculty of these changes.

1. Since we are still under a Shelter-in-Place County Order, 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 should continue virtually. Any follow-up visits for essential treatment trials or clinical observational studies should be postponed or conducted virtually where possible.

2. Ongoing treatment studies that provide critical therapeutic support for our patients, and/or where cessation of the treatment could negatively impact patient outcomes, safety or care, can continue with in-person visits, given the Principal Investigator/Project Lead has obtained the required approvals described in the Approvals Section below.

3. 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 outcomes, safety or care, can continue with in-person visits, given the Principal Investigator/Project Lead has obtained the required approvals described in the Approvals Section below.

4. New treatment studies or new clinical observation studies requiring in-person visits, that a Principal Investigator/Project Lead and their Chair and/or Institute Director determine could negatively impact patient outcomes, safety or care if they were not to take place, can be initiated. The Principal Investigator/Project Lead needs to follow the procedures for obtaining the required approvals as described in the Approvals Section below.

5. New or ongoing clinical research studies involving outpatients or inpatients who are already coming into Stanford Health Care or Stanford Children’s Health for medical care, can occur if they a) do not interfere with the patient’s medical care; b) can be conducted by essential personnel, including CRCs, who are appropriately trained in the patient care setting, with all appropriate safeguards in place and appropriate trainings completed; and c) have all required approvals, as described below. The Principal Investigator/Project Lead needs to follow the procedures for obtaining the required approvals as described in the Approvals Section below.

6. The procedures for obtaining permission for Covid-19 Clinical or Basic research remain unchanged. Investigators should follow the guidance provided by the Vice Provost and Dean for Research, Kam Moler, distributed on March, 29, 2020.

**IMPORTANT CONSIDERATIONS FOR THE APPROVAL PROCESS:**

1) For all categories of research specified above, in order to proceed, approval needs to be obtained a) from the Department Chair or designee, and/or Institute Director, and
verification that the research can occur in the Stanford Health Care or Stanford Children’s Health setting; and b) final approval should be obtained from the Office of the Senior Associate Dean for Research, School of Medicine, Dr. Ruth O’Hara.

2) With respect to new or ongoing clinical trials or clinical research studies involving patients who are already coming into Stanford Health Care or Stanford Children’s Health for medical care, we cannot accommodate all such studies at once. We have to proceed in an incremental, paced manner. Departmental Chairs and/or Institute Directors will have to decide which Clinical Trials and Clinical Research can proceed first.

3) An important consideration will include the number of essential personnel required for the study. In order to protect our patients and each other, all essential personnel who will be patient facing will be asked to be tested for Covid-19 through Occupational Health in Stanford Medicine.

4) The process for testing will be organized and centralized through the Office of the Senior Associate Dean for Research, under the direction of Jennifer Brown, the Director of Clinical Research Quality. Once an investigator has obtained all required approvals, they or their Chair or Institute Director should contact the Office of the Senior Associate Dean for Research, School of Medicine, at Pooneh.Fouladi@stanford.edu, and a) provide their approvals; b) identify the essential personnel who will working on the study; c) specify those who will be patient facing; and d) provide us with the name of the supervisor for all essential personnel. Jennifer Brown, Director of Clinical Research Quality, will contact each individual essential personnel to organize their testing through Occupational Health in Stanford Medicine and communicate their results.

5) The SAD-R, Dr. Ruth O’Hara, will then provide the final approval for the Clinical Trials or Clinical Research to proceed.

IMPORTANT REMINDERS:

A. All Research Personnel and Faculty Should Complete the Following Training:

   Course Completion: COVID-19 Hygiene Best Practices (EHS-2470-WEB)

B. All necessary safety precautions as outlined on the EH&S website should be taken for all in-person visits, including use of PPE and social distancing. Jennifer Brown, Director of the Clinical Research Quality Unit will coordinate with all essential personnel, in coordination with their direct supervisor, in order to ensure that all necessary safety precautions are being implemented. Jennifer Brown will also be responsible for the coordination of the testing through Occupational Health in Stanford Medicine.
C. Investigators 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.

D. Modifications to 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.

E. Where additional guidance is needed, please do not hesitate to contact the Senior Associate Dean for Research in the School of Medicine, Dr. Ruth O’Hara, at Pooneh.Fouladi@stanford.edu