COVID Resource Page

Announcement from the COVID-19 Clinical Research Review Panel

Researchers considering any COVID-19 clinical research, including studies that require Institutional Review Board (IRB) approval as well as quality improvement projects, are required to complete a short survey at COVID-19 Clinical Research Review [1].

The COVID-19 Clinical Research Review Panel ? created by Ruth O?Hara, PhD, senior associate dean for research, and led by Kenneth Mahaffey, MD, vice chair of clinical research in the Department of Medicine, and Upinder Singh, MD, chief of infectious diseases in the Department of Medicine ? will review the proposals and adjudicate for prioritization. The panel will also help foster collaboration and identify potential synergies across proposed clinical research studies and will evaluate efforts for ensuring research personnel and participant safety.

You may submit your protocol to IRB in parallel with the COVID-19 Clinical Research Review survey. However, the COVID-19 Clinical Research Review Panel will need to complete their review of your survey before IRB approval is granted. If you have any questions about the process, please contact Pooneh Fouladi at pooneh.fouladi@stanford.edu [2].

Per FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic: [3]

- "Sponsors and clinical investigators are encouraged to engage with IRBs/IEC as early as possible when urgent or emergent changes to the protocol or informed consent are anticipated as a result of COVID-19. Such changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants (e.g., to limit exposure to COVID-19) may be implemented without IRB approval or before filing an amendment to the IND or IDE, but are required to be reported afterwards."

- "If scheduled visits at clinical sites will be significantly impacted, certain investigational products, such as those that are typically distributed for self-administration, may be amenable to alternative secure delivery methods. For other investigational products that are normally administered in a health care setting, consulting FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel) is recommended. In all cases, existing regulatory requirements for maintaining investigational product accountability remain and should be addressed and documented.

Note that the process for Emergency Use [4] of an experimental drug or device remains the same.

Additional Considerations for COVID Research

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Local Review Requirements for Human Subjects Research [5]

- Recommended language for return of COVID results [6]

- Stanford EH&S COVID-19 Research Restart Plan [7] - Beginning on June 22, 2020, Stanford Research will enter Stage 2. This Research Recovery Handbook focuses on guidance for Stages 0 ? 2. It currently covers laboratories, libraries, and field research, and will be expanded for other areas of scholarship and updated as conditions develop.

- Stanford Cancer Institute Remote Consenting of Adults Guideline [8]

- Stanford CRQ Remote Monitoring tools:

  1. WI-007 Remote Monitoring Using Stanford Medicine Box [9] - a work instruction for CRCs/CRMs/etc.
  2. FRM-024 Instructions to Monitors on Accessing Research Files in Stanford Medicine Box [10] - this form consists of instructions for the monitor as well as an agreement form and confidentiality agreement that the monitor will need to sign and return to their designated site contact prior to their remote monitoring visit.

Source URL: https://researchcompliance.stanford.edu/panels/hs/COVID

Links
[1] https://app.smartsheet.com/b/form/324e5813005e465cad070e46fd5de753
[2] mailto:pooneh.fouladi@stanford.edu
[3] https://www.fda.gov/media/136238/download
[6] https://stanfordmedicine.box.com/shared/static/63y7hutheqz6mwahc3mcjoe0o3trkuq8.docx
[9] https://stanfordmedicine.box.com/s/4vz0ng59xeqb37200a7panyyp80p9j3t
[10] https://stanfordmedicine.box.com/s/cfcwym3dp0qp8l4z90pf89e16tju3s1b