

## COVID Resource Page

### Research in Response to COVID-19

**[Stanford Research Recovery Handbook](#) [1] - Includes updates on Stage 3 Clinical Human Subjects**

- **Research and Non-Clinical Human Subjects Research**

**Update on Clinical and Non-Clinical Human Subject Research:** COVID-related standard operating procedures (SOPs) are no longer needed for domestic clinical and non-clinical human subjects research projects that have an IRB-approved requirement for participants to be fully vaccinated or receive a negative COVID test within 72 hours before the research is conducted. Otherwise, SOPs continue to be necessary. Given the large number of protocols to be modified, the IRB can only make these changes at the point of the annual renewal of your eProtocol or when you are submitting an unrelated modification.

The same policies and procedures apply to human subjects research requiring domestic travel. A separate approval for international travel and international human subjects field research remains in effect until further notice. SOPs can be found in the research recovery handbook for [clinical](#) [2], [non-clinical](#) [3], and [non-clinical off-campus](#) [4] human subjects research. Local departments will have full discretion to approve the SOPs.

**Consent Language:** If you are coming in-person to research visits, you are required to be fully vaccinated?2 doses (1 for Johnson and Johnson), 2 weeks out and to provide proof of your vaccination (e.g., CDC COVID-19 Vaccination Card, e-Health record, etc.) to the researcher prior to study

- participation. Alternately, you can provide a negative COVID test within 72 hours of your visit. ?

**Consent Forms of all Studies involving COVID-19 Research -** The following language must be included:

Due to the coronavirus public health emergency, the federal government has issued a Declaration that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study. If the Declaration applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this ?Countermeasures Injury Compensation Program? please go to

- <https://www.hrsa.gov/cicp/about/index.html> or call 1-855-266-2427.

Contact the Research Participation team at [EngageParticipants@stanford.edu](mailto:EngageParticipants@stanford.edu) [5] to list your study in the [Stanford COVID-19 Study Directory](#) [6].

### 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](#) [7].

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](mailto:pooneh.fouladi@stanford.edu) [8].

### **Per FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic:** [9]

- "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](#) [10] of an experimental drug or device remains the same.

### **Additional Considerations for COVID Research**

- [Local Review Requirements for Human Subjects Research](#) [11]
- **Consent Forms of Studies involving COVID-19 Research**

-Must include the language below:

Due to the coronavirus public health emergency, the federal government has issued a Declaration that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study. If the Declaration applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this ?Countermeasures Injury Compensation Program? please go to <https://www.hrsa.gov/cicp/about/index.html> or call 1-855-266-2427.

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## Recommended language for return of COVID results [12]

- **Stanford EH&S COVID-19 Research Restart Plan** [13] - 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** [14]
  - **Stanford CRQ Remote Monitoring tools:**
    1. **WI-007 Remote Monitoring Using Stanford Medicine Box** [15]? a work instruction for CRCs/CRMs/etc.
    2. **FRM-024 Instructions to Monitors on Accessing Research Files in Stanford Medicine Box** [16] ? 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.
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**Source URL:** <https://researchcompliance.stanford.edu/panels/hs/COVID>

### Links

[1] <https://cardinalrecovery.stanford.edu/research/research-recovery/>

[2] <https://cardinalrecovery.stanford.edu/research/research-recovery/#clinical-human-subjects-research.3>

[3] <https://cardinalrecovery.stanford.edu/research/research-recovery/#non-clinical-human-subjects-research.3>

[4] <https://cardinalrecovery.stanford.edu/research/research-recovery/#non-clinical-human-subjects-research.4>

[5] <mailto:EngageParticipants@stanford.edu>

[6] <http://stan.md/covid19-participate>

[7] <https://app.smartsheet.com/b/form/324e5813005e465cad070e46fd5de753>

[8] <mailto:pooneh.fouladi@stanford.edu>

[9] <https://www.fda.gov/media/136238/download>

[10] <https://researchcompliance.stanford.edu/panels/hs/forms/emergency>

[11] <https://stanfordmedicine.box.com/shared/static/2hukpmgrja5ytq5rai74jt5720ywk68f.docx>

[12] <https://stanfordmedicine.box.com/shared/static/63y7hutheqz6mwahc3mcjoe0o3trkuq8.docx>

[13] <https://ehs.stanford.edu/returntoresearch>

[14]

[http://med.stanford.edu/content/dam/sm/ccto/sunet\\_id\\_resources/regulatory\\_documents/sop/Remote\\_Consent\\_of\\_Adults\\_](http://med.stanford.edu/content/dam/sm/ccto/sunet_id_resources/regulatory_documents/sop/Remote_Consent_of_Adults_)

[15] <https://stanfordmedicine.box.com/s/4vz0ng59xeqb37200a7panyyp80p9j3t>

[16] <https://stanfordmedicine.box.com/s/cfcwym3dp0qp8l4z90pf89e16tju3s1b>