Welcome

Research in Response to COVID-19


- **New 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.

- **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 [5]. For more information, click here [6].
Contact the Research Participation team at EngageParticipants@stanford.edu [7] to list your study in the Stanford COVID-19 Study Directory [8].

**ADDITIONAL COVID RESOURCES [6]**

- Satisfaction Survey Results Panel Year 2020-2021 [9]
- Satisfaction Survey Results Q4 Panel Year 2020-2021 [10]
- **What's New**
  - Training videos posted HERE [12].
  - New Common Rule effective January 21, 2019 [14].
  - Sample eProtocol Template Forms [15].
  - Two new eProtocol [16] forms, Single Patient IND and Humanitarian Use Device (HUD) [17]
  - European Union General Data Protection Regulation (GDPR) is now in effect. Learn more [18].
  - Single IRB (sIRB) [19]
  - ClinicalTrials
    - Changing policies impact NIH-funded studies involving human subjects [20]. In your proposal application packet, be sure to complete the ?R&R Other Project Information? form page before you complete the ?PHS Human Subjects and Clinical Trials Information? form page as the first will populate the second. Please view this 9 min YouTube video: PHS Human Subjects and Clinical Trial Information Form Walk-through [21].
  - ClinicalTrials.gov [22]
    - CRQ's ClinicalTrials.Gov resources page [23]

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<td>• For Researchers [24]</td>
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<td>• Consent Process [25]</td>
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<tr>
<td>• Human Subjects Research (HSR) Determination application is available in eProtocol [16]. Attach this completed form [26]. (More Information [27])</td>
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<th>Consent Templates, Forms, eProtocol attachments</th>
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<td>• Medical &amp; Nonmedical - assent, phone scripts and screens, etc. [29]</td>
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About the IRB (the Administrative Panels on Human Subjects Research)

Charge to the IRBs

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

Links
[1] https://cardinalrecovery.stanford.edu/research/research-recovery/
[7] mailto:EngageParticipants@stanford.edu
[12] https://researchcompliance.stanford.edu/panels/hs/forms/training
[16] https://eprotocol.stanford.edu/
[18] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs%23gdpr
[20] https://stanfordmedicine.box.com/shared/static/umvwu8n8cms8o7db4bt7gpot3x41tgf.pdf
[21] https://www.youtube.com/watch?v=nz9NWFhYOG8&amp;list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFPEmQK&amp;index=1
[22] https://clinicaltrials.gov/
[23] https://med.stanford.edu/spectrum/study-team-resources/clinical-research-quality-crq/crq-clinicaltrials-gov-support-services.html
[25] https://researchcompliance.stanford.edu/panels/hs/forms/forms/consent
[26] https://stanfordmedicine.box.com/shared/static/jm5gac2qyhz80glimds8uas32fwn87ce.docx
[27] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/need
[29] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates
[31] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs
[33] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#Training
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