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 to list your study in the Stanford COVID-19 Study Directory.

ADDITIONAL COVID RESOURCES

• Satisfaction Survey Results Panel Year 2019-2020
• Satisfaction Survey Results Q3 Panel Year 2020-2021

What's New

○ Training videos posted HERE for electronic consent signatures
○ New Common Rule effective January 21, 2019
○ Sample eProtocol Template Forms
○ Two new eProtocol forms, Single Patient IND and Humanitarian Use Device (HUD)
○ European Union General Data Protection Regulation (GDPR) is now in effect. Learn more.
○ Single IRB (sIRB)
○ ClinicalTrials
  ▪ Changing policies impact NIH-funded studies involving human subjects
  In your proposal application packet, be sure to complete the PHS Human Subjects and Clinical Trials 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 You Tube video: PHS Human Subjects and Clinical Trial Information Form Walk-through.
○ ClinicalTrials.gov
  ▪ CRO's Clinical Trials.Gov resources page

Quick links for researchers

Getting started

• For Researchers
• Consent Process
• Human Subjects Research (HSR) Determination application is available in eProtocol. Attach this completed form. (More Information)

Consent Templates, Forms, eProtocol attachments

• Medical - consents, minimal risk samples, short form
• Nonmedical - consents, parental permission
• Medical & Nonmedical - assent, phone scripts and screens, etc.
• eProtocol Required Attachments (VA, international research, etc.)
• Sample eProtocol Applications

FAQs

Basics | Training | Protocol Management | Single IRB | Genomic Data Sharing | Cadavers or Deceased Individuals | Certificate of Confidentiality | GDPR | Other/Special Circumstances

• About the IRB (the Administrative Panels on Human Subjects Research)
• Charge to the IRBs