Welcome

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]. For more information, click here [2].

Research in Response to COVID-19


- **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 [4] to list your study in the Stanford COVID-19 Study Directory [5].

- **Human subject research community participant expansion:** IRB-approved clinical and non-clinical longitudinal and cross-sectional in-person Human Subjects Research on campus with community participants over the age of 65 years is now allowed if they have been fully vaccinated for over two weeks and can provide proof of their vaccination to the researcher prior to study participation.

  You may implement this process immediately and update the protocol at the next event (i.e., continuing review or modification) to reflect this change. The IRB modification should include an update to the consent form to inform participants over the age of 65 of the requirement for in-person visits. Below is an example of the consent form language:

  *If you are over 65 years of age and require in-person research visits, you are required to be fully vaccinated?2 doses, 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.*

**ADDITIONAL COVID RESOURCES** [2]

- **Satisfaction Survey Results Panel Year 2019-2020** [6]
• Satisfaction Survey Results Q2 Panel Year 2020-2021 [7]

• What’s New
  • Training videos posted HERE [8].
  • Adobe Sign Information and Instructions [9] for electronic consent signatures
  • New Common Rule effective January 21, 2019 [10].
  • Sample eProtocol Template Forms [11].
  • Two new eProtocol [12] forms, Single Patient IND and Humanitarian Use Device (HUD) [13].
  • European Union General Data Protection Regulation (GDPR) is now in effect. Learn more [14].
  • Single IRB (sIRB) [15]
  • ClinicalTrials
    ▪ Changing policies impact NIH-funded studies involving human subjects [16] 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 You Tube video: PHS Human Subjects and Clinical Trial Information Form Walk-through [17].
    ▪ ClinicalTrials.gov [18]
      ▪ CRQ’s Clinical Trials.Gov resources page [19]

Quick links for researchers

Getting started

• For Researchers [20]
• Consent Process [21]
• Human Subjects Research (HSR) Determination application is available in eProtocol [12]. Attach this completed form [22]. (More Information [23])

Consent Templates, Forms, eProtocol attachments

• Medical - consents, minimal risk samples, short form [24]
• Nonmedical - consents, parental permission [25]
• Medical & Nonmedical - assent, phone scripts and screens, etc. [26]
• eProtocol Required Attachments [11] (VA, international research, etc.)
• Sample eProtocol Applications [27]

FAQs [28]


• About the IRB [38] (the Administrative Panels on Human Subjects Research)
• Charge to the IRBs [39]

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

Links
[1] https://app.smartsheet.com/b/form/324e5813005e465cad070e46fd5de753