Welcome

The Research Compliance Office (RCO) will be closed during Stanford? s Winter Closure from Monday, December 20, 2021 through Sunday, January 2, 2021. Major (Presented) Modifications and Continuing Review submissions must be submitted by November 15, 2021. Minor modifications will be reviewed prior to winter closure. The RCO will provide critical support on a limited schedule and email messages and HelpSU tickets [1] will be monitored during this time. Please contact your IRB [2] Panel Manager or IRB Education [3] if you have any general questions.

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 [5], non-clinical [6], and non-clinical off-campus [7] 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
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 [8]. For more information, click here [9].


ADDITIONAL COVID RESOURCES [9]

- Satisfaction Survey Results Panel Year 2020-2021 [12]
- Satisfaction Survey Results Q4 Panel Year 2020-2021 [13]
- What’s New
  - Training videos posted HERE [14].
  - New Common Rule effective January 21, 2019 [16].
  - Sample eProtocol Template Forms [17].
  - Two new eProtocol [18] forms, Single Patient IND and Humanitarian Use Device (HUD) [19]
  - European Union General Data Protection Regulation (GDPR) is now in effect. Learn more [20].
  - Single IRB (sIRB) [21]
  - ClinicalTrials
    - Changing policies impact NIH-funded studies involving human subjects [22]. 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 [23].
    - ClinicalTrials.gov [24]
    - CRQ’s Clinical Trials.Gov resources page [25]

Quick links for researchers

Getting started

- For Researchers [26]
- Consent Process [27]
- Human Subjects Research (HSR) Determination application is available in eProtocol [18]. Attach this completed form [28]. (More Information [29])

Consent Templates, Forms, eProtocol attachments

- Medical - consents, minimal risk samples, short form [30]
- Nonmedical - consents, parental permission [31]
- Medical & Nonmedical - assent, phone scripts and screens, etc. [32]
- eProtocol Required Attachments [17] (VA, international research, etc.)
- Sample eProtocol Applications [33]