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].

**ADDITIONAL COVID RESOURCES** [2]

- Satisfaction Survey Results Panel Year 2019-2020 [6]
- Satisfaction Survey Results Q1 Panel Year 2020-2021 [7]
- What's New
  - Training videos posted HERE [8].
  - New Common Rule effective January 21, 2019 [9].
  - Informed consent templates [10] have been updated to include the new requirement to provide key information as a concise summary at the beginning of the consent form, the new basic element of consent regarding future use, and the new additional elements of consent as applicable. (The concise summary is not required for Minimal Risk or Non-medical consents.)
  - eProtocol is rolling out a new user interface (UI) on the updated Exempt form that includes the new Common Rule Exempt categories. While the new UI has a different appearance, the application questions have not changed. The Exempt form is the only IRB form using the new UI at this time.
The revised Common Rule requires that for any clinical trial conducted or supported by a Common Rule department or agency, one consent form must be posted on a publicly available federal website after recruitment closes and no later than 60 days after the last study visit. The consent form must have been used to enroll subjects in order to satisfy this new provision. Click here [13] for details.

- Sample eProtocol Template Forms [14].
- European Union General Data Protection Regulation (GDPR) is now in effect. Learn more [17].
- Single IRB (sIRB) [18]
- ClinicalTrials
  - Revised Intake Process for Industry Clinical Trials [19]
  - 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 You Tube video: PHS Human Subjects and Clinical Trial Information Form Walk-through [21].
- ClinicalTrials.gov [22]
- CRQ’s Clinical Trials.Gov resources page [23]

Quick links for researchers

Getting started

- For Researchers [24]
- Consent Process [25]
- Human Subjects Research (HSR) Determination application is available in eProtocol [15]. Attach this completed form [26]. (More Information [27])

Consent Templates, Forms, eProtocol attachments

- Medical - consents, minimal risk samples, short form [10]
- Nonmedical - consents, parental permission [28]
- Medical & Nonmedical - assent, phone scripts and screens, etc. [29]
- eProtocol Required Attachments [14] (VA, international research, etc.)
- Sample eProtocol Applications [30]

FAQs [31]


- About the IRB [41] (the Administrative Panels on Human Subjects Research)
- Charge to the IRBs [42]

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

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