Welcome

Winter Closure

The Research Compliance Office (RCO) will be closed during Stanford’s Winter Closure from Monday, December 14, 2020 through Sunday, January 3, 2021. New protocols, Major Modifications and Continuing Review submissions must be submitted by November 12th, 2020. Minor modifications will be reviewed prior to winter closure, when possible. The RCO will provide critical support on a limited schedule and email messages and HelpSU [1] tickets will be monitored during this time. Please contact your IRB [2] Panel Manager or IRB Education [3] if you have any general questions.

Announcement from the 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 [4]. For more information, click here [5].

Research in Response to COVID-19

- The Research Compliance Office (IRB, SCRO, APLAC) is operating with a full staff and conducting protocol review business as usual. Incoming questions, help tickets or other support services are also being maintained.

In an effort to eliminate apparent immediate hazards to subjects (45 CFR 46.108(3)(iii)) and the Stanford community, all in-person visits for non-essential human research activities must be postponed, while preserving critical activity on interventional treatment trials or critical clinical research. In light of this urgency around COVID-19, Stanford’s IRB is not requiring prior review of some protocol changes, e.g., implementing video/phone visits, mailing of study medications, or other changes designed to protect participant safety.

Understanding that resources must be prioritized, please track these changes and file a modification in eProtocol [6] when your schedule allows. The IRB is available to assist you with these modifications.

ADDITIONAL COVID RESOURCES [5]

- Survey Results (2019-2020 Panel Year Q3 Results) [7]
- What’s New
  - RCO is moving to 1705 El Camino Real, Palo Alto CA 94306 / SU ID Mail 5579 (effective 1/1/2020)
  - New Common Rule effective January 21, 2019 [8].
    - Informed consent templates [9] 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.

New 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 [12] for details.

- Sample eProtocol Template Forms [13].
- European Union General Data Protection Regulation (GDPR) is now in effect. Learn more [15].
- Single IRB (sIRB) [16]
- ClinicalTrials
  - Revised Intake Process for Industry Clinical Trials [17]
  - Changing policies impact NIH-funded studies involving human subjects [18] 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 [19].
- ClinicalTrials.gov [20]
  - CRQ’s Clinical Trials.Gov resources page [21]

Quick links for researchers

Getting started

- For Researchers [22]
- Consent Process [23]

Consent Templates, Forms, eProtocol attachments

- Medical - consents, minimal risk samples, short form [9]
- Nonmedical - consents, parental permission [26]
- Medical & Nonmedical - assent, phone scripts and screens, etc. [27]
- eProtocol Required Attachments [13] (VA, international research, etc.)
- Sample eProtocol Applications [28]

FAQs [29]


- About the IRB [39] (the Administrative Panels on Human Subjects Research)
- Charge to the IRBs [40]