Welcome

- Updates to Research in Response to COVID-19

The IRB has received questions from researchers about the appropriate process for making changes to research studies in light of COVID-19. Please see procedures below:

- Regulations require prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.108(3)(iii)). For changes made to the research in order to eliminate apparent immediate hazards to participants, submit a prompt report [1] in eProtocol [2] within 10 working days of the event.
- For all other prospective changes to human subjects research, submit a modification in eProtocol [2] for IRB review and approval, prior to implementation.

If your study has been reviewed by an external Single IRB (sIRB), please work with that responsible reviewing sIRB.

For questions related to research operations and communication with participants, please refer to Stanford Health Alerts [3] and Stanford Health Care [4] webpages. Note that the process for Emergency Use [5] of an experimental drug or device remains the same.


- Survey Results (2019-2020 Panel Year Q1 Results) [8]
- 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 [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 [16].
Single IRB (sIRB) [17]
  ▪ Relying on a sIRB [18] and sIRB SOP [19]  
  ▪ NCI CIRB - the NCI Central IRB Initiative [20]
ClinicalTrials
  ▪ Revised Intake Process for Industry Clinical Trials [21]  
  ▪ 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]

Consent Templates, Forms, eProtocol attachments
- Medical - consents, minimal risk samples, short form [10]
- Nonmedical - consents, parental permission [30]
- Medical & Nonmedical - assent, phone scripts and screens, etc. [31]
- eProtocol Required Attachments [14] (VA, international research, etc.)
- Sample eProtocol Applications [32]

FAQs [33]

- About the IRB [43] (the Administrative Panels on Human Subjects Research)
- Charge to the IRBs [44]

Source URL: https://researchcompliance.stanford.edu/panels/hs
Links
[1] https://stanfordmedicine.box.com/shared/static/qbsi8u8h47qsotxhdpuzz50xlrqa0sgo.pdf