Welcome

- Survey Results (2018-2019 Panel Year Q3 Results) [1]
- What’s New
  - New Common Rule effective January 21, 2019 [2].
    - 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 [3] for details.
  - New 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 Exempt Form [4] in eProtocol (video [5])
  - Informed consent templates [6] 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.)
  - Sample eProtocol Template Forms [7].
  - European Union General Data Protection Regulation (GDPR) is now in effect. Learn more [10].
  - Single IRB (sIRB) [11]
    - Relying on a sIRB [12] and sIRB SOP [13]
    - NCI CIRB - the NCI Central IRB Initiative [14]
  - ClinicalTrials.gov
    - Revised Intake Process for Industry Clinical Trials [15]
    - 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].

Quick links for researchers

Getting started

- For Researchers [18]
- Consent Process [19]
Consent Templates, Forms, eProtocol attachments

- Medical - consents, minimal risk samples, short form [6]
- Nonmedical - consents, parental permission [22]
- Medical & Nonmedical - assent, phone scripts and screens, etc. [23]
- eProtocol Required Attachments [7] (VA, international research, etc.)
- Sample eProtocol Applications [24]

FAQs [25]

- About the IRB [35] (the Administrative Panels on Human Subjects Research)
- Charge to the IRBs [36]

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

Links
[8] https://eprotocol.stanford.edu/
[12] https://researchcompliance.stanford.edu/panels/hs/forms/researchers#ext_IRBs
[14] https://researchcompliance.stanford.edu/panels/hs/forms/researchers#nci_cirb
[15] https://stanfordmedicine.box.com/shared/static/7jlh5qgele0tm9khd8pmkpytirjrw8vn.pdf
[16] https://stanfordmedicine.box.com/shared/static/umvwu8n8cms8o7db4bt7gpot3x41tgf.pdf
[17] https://www.youtube.com/watch?v=nz9NWFrYOG8&list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFPEmQK&index=1
[18] https://researchcompliance.stanford.edu/panels/hs/forms/researchers
[21] https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers#need
[22] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/nonmedical
[23] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates
[26] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#basics
[27] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#Training