Welcome

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 [1].

The COVID-19 Clinical Research Review Panel, created by Ruth O’Hara, PhD, senior associate dean for research, and led by Kenneth Mahaffey, MD, vice chair of clinical research in the Department of Medicine, and Upinder Singh, MD, chief of infectious diseases in the Department of Medicine, will review the proposals and adjudicate for prioritization. The panel will also help foster collaboration and identify potential synergies across proposed clinical research studies and will evaluate efforts for ensuring research personnel and participant safety.

You may submit your protocol to IRB in parallel with the COVID-19 Clinical Research Review survey. However, the COVID-19 Clinical Research Review Panel will need to complete their review of your survey before IRB approval is granted. If you have any questions about the process, please contact Pooneh Fouladi at pooneh.fouladi@stanford.edu [2].

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 [3] when your schedule allows. The IRB is available to assist you with these modifications.

Per [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic:][4]

- "Sponsors and clinical investigators are encouraged to engage with IRBs/IEC as early as possible when urgent or emergent changes to the protocol or informed consent are anticipated as a result of COVID-19. Such changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants (e.g., to limit exposure to COVID-19) may be implemented without IRB approval or before filing an amendment to the IND or IDE, but are required to be reported afterwards."

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"If scheduled visits at clinical sites will be significantly impacted, certain investigational products, such as those that are typically distributed for self-administration, may be amenable to alternative secure delivery methods. For other investigational products that are normally administered in a health care setting, consulting FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel) is recommended. In all cases, existing regulatory requirements for maintaining investigational product accountability remain and should be addressed and documented.

?Note that the process for Emergency Use [5] of an experimental drug or device remains the same.


• Survey Results (2019-2020 Panel Year Q2 Results) [10]
• What's New
  ○ New: RCO is moving to 1705 El Camino Real, Palo Alto CA 94306 / SU ID Mail 5579  (effective 1/1/2020)
     ▪ Informed consent templates [12] 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.)
     ▪ New Exempt Form [13] in eProtocol (video [14])
     ▪ 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 [15] for details.
  ○ Sample eProtocol Template Forms [16].
  ○ European Union General Data Protection Regulation (GDPR) is now in effect. Learn more [18].
  ○ Single IRB (sIRB) [19]
     ▪ Relying on a sIRB [20] and sIRB SOP [21]
     ▪ NCI CIRB - the NCI Central IRB Initiative [22]
  ○ ClinicalTrials
     ▪ Revised Intake Process for Industry Clinical Trials [23]
     ▪ Changing policies impact NIH-funded studies involving human subjects [24]  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 [25].
  ○ ClinicalTrials.gov [26]
     ▪ CRQ's Clinical Trials.Gov resources page [27]
Getting started

- **For Researchers** [28]
- **Consent Process** [29]
- Human Subjects Research (HSR) Determination application is available in eProtocol [3]. Attach this completed form [30]. (More Information [31])

Consent Templates, Forms, eProtocol attachments

- **Medical** - consents, minimal risk samples, short form [12]
- **Nonmedical** - consents, parental permission [32]
- **Medical & Nonmedical** - assent, phone scripts and screens, etc. [33]
- **eProtocol Required Attachments** [16] (VA, international research, etc.)
- **Sample eProtocol Applications** [34]

**FAQs** [35]


- **About the IRB** [45] (the Administrative Panels on Human Subjects Research)
- **Charge to the IRBs** [46]

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

Links

[1] https://app.smartsheet.com/b/form/324e5813005e465cad070e46fd5de753
[2] mailto:pooneh.fouladi@stanford.edu
[6] mailto:irbeducation@stanford.edu
[18] https://researchcompliance.stanford.edu/.../panels/hs/forms/forms-templates/faqs%23gdpr
[19] https://researchcompliance.stanford.edu/panels/hs/forms/researchers#single_irb
[20] https://researchcompliance.stanford.edu/panels/hs/forms/researchers#ext_IRBs
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