Stanford
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For Researchers

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  - Presentations [5] (education) provided to the research community
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Common Rule Changes

OHRP published the Final Rule for the Protection of Human Subjects in research on 1/19/2017. This is the first major revision of the Common Rule since 1991. The Rule became effective on 1/21/2019. The Stanford Common Rule [7] page provides implementation information.

Training

- "Let the IRB Staff Come to You!" [8]: Researchers can arrange for 1-on-1 or group sessions
- For research participants, patients, and others interested in medical practice research - a new resource on the Spectrum website: Research on Medical Practices (ROMP) [9] and ROMP Videos [10].

Do I need an IRB Submission?

- Does My Project Need IRB Review? [11] ( )
- [12]Determination of Human Subject Research Application [12] ( ) This form should be submitted in eProtocol as a Human Subjects Research (HSR) Determination.

  To submit a 'Determination of Human Subject Research' form in eProtocol [13], select 'Create a Protocol' on the 'My Dashboard' webpage. After completing the requested information, select 'Human Subject Research (HSR)' as your type of review. Complete the application and attach the Human Subject Research (HSR) Determination Form

[12] for review (there is also a link to this form in the attachments section of the protocol application).

Possible results of the HSR Determination review are:

- Not Research (e.g. QA/QI or a case study)
- Not Human Subjects Research
- Human Subjects Research

After the IRB has made its determination, the IRB will "Keep" or "Withdraw" the HSR application. Withdrawn applications DO meet the definition of human subjects research, and require that an IRB protocol be submitted and approved prior to any research activities being conducted, including recruiting or consenting prospective participants.

To view the IRB's determination in eProtocol:

Go to 'My Dashboard' and select 'Non-Active Protocols'. Open the protocol number in question. Click the bottom left red tab, "Print View" for a PDF of the HSR application -- the HSR determination will be on page 2.

- IRB Review Type: What is it and why do I need to know? [14]

Forms and Processes

- Forms & Consent Templates [15]
- Consent [16]
- Recruitment [17]
- Emergency Use of a Test Article [18]

Medical Research

- Medical Application Process [19]
- Filling out the Medical Protocol Application [20]
- Sample Medical eProtocol applications [21]

Clinical trial documents: The following checklists are from the FDA E6 Consolidated Guidance for Good Clinical Practice [22]:

- Checklist: Before the Clinical Phase of the Trial Commences [23] (section 8.2) - Documents on file before the trial formally starts
- Checklist: During the Clinical Conduct of the Trial [24] (section 8.3) - Documents added to the files during the trial

Nonmedical Research

- Nonmedical Application Process [25]
- Information About eProtocol Sections for Nonmedical Applications [26]
- Sample Nonmedical eProtocol applications [27]

Single IRB (sIRB)

NIH Funded Studies

NIH policy [28] on the Use of a Single Institutional Review Board for Multi-Site Research will be effective January 25, 2018.

- All sites participating in multi-site studies involving non-exempt human subjects research funded by the NIH

must use a single IRB (sIRB). Applicants must include a plan for the use of a sIRB in their applications/proposals submitted to the NIH on or after January 25, 2018.

- Costs associated with the sIRB review may be included as direct costs in the application budget. Work with your Research Process Manager [29] prior to submitting your proposal to NIH. NIH FAQs on sIRB costs. [30]
- Guidance on Exceptions to the NIH Single IRB Policy (NOT-OD-18-003 [31])
- Guidance of Implementation of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-18-004 [32])
- Scenarios to Illustrate the Use of Direct and Indirect Costs for Single IRB Review under the NIH Policy on the Use of a Single IRB for Multi-site Research (NOT-OD-16-109 [33])

Stanford as Prime or Lead Site

When Stanford is the Prime Awardee or the lead site on a multi-site study requiring sIRB, you will need to consider the following reviewing IRBs to include in your proposal submitted to the NIH for the use of an sIRB:

- Commercial IRB, e.g., Quorum Review IRB [34]
- Trial Innovation Network Central IRB [35]
- Another academic IRB (i.e., one of the other participating institutions)

Will the single IRB that is identified in the NIH application/proposal be evaluated during peer review?(NIH FAQs [36])

- No. The proposed single IRB will not be evaluated as part of the peer review process and will not affect the overall assigned score of an application/proposal or the overall rating of the acceptability of the Protection of Human Subjects section. Peer reviewers may note if the plan to comply with the NIH single IRB policy is not included in the application/proposal but this will not impact the score.

Per NIH's Single IRB and Exception Process Webinar [37] (October 18, 2017), the sIRB of record does not have to be the IRB of the parent award.

Relying on a Single IRB (sIRB)

Stanford's IRB may agree to rely on a single IRB (sIRB) for multisite studies to provide initial and ongoing regulatory reviews. The reliance terms are outlined in an IRB Authorization Agreement (IAA). Stanford has signed on to SMART IRB [38], which supports IRB reliance across the nation. The sIRB is responsible for reviews required by federal regulations at 45 CFR 46, and 21 CFR 50 and 56 (initial review, continuing review, modifications, reportable events). When Stanford?s IRB relies on a sIRB, it retains responsibility to:

- ensure investigator compliance with the protocol,
- oversee the sIRB's determinations,
- ensure applicable federal and state regulations, and
- ensure Stanford policy.

Stanford's IRB also bears responsibility for the local conduct of sIRB studies, including managing noncompliance and unanticipated problems, ensuring training, study monitoring, local ancillary requirements, managing reliance agreements, and handling study specific issues.

Reliance on a sIRB is considered on a case-by-case basis for high risk studies when not mandated by NIH Single IRB policy. Some examples might include first-in-human drug or device studies, certain biological agents or Recombinant DNA Vector studies, or studies that involve stem cells or hESC. Stanford?s IRB will not rely on a sIRB when Stanford is the sole site.

The Protocol Director (PD) is required to submit a sIRB eProtocol [39] application to request reliance on a sIRB. When the (1) sIRB eProtocol application and the (2) reliance IAA are complete, a Reliance Letter will be issued through eProtocol. Please see the sIRB SOP [40] for more detailed information. See here [41] for additional Relying PI responsibilities.

[42]

NCI CIRB - the NCI Central IRB Initiative

Protocols Qualifying for CIRB Review

The Adult and Pediatric CIRBs are the IRBs of record for certain adult and pediatric national multi-center cooperative oncology group cancer treatment trials.

- Instruction Manual for Worksheet Completion in IRBManager [43]

More information

- NCI CIRB Website [44]
- CCTO SoP for relying on a Central IRB [45]
- Stanford University CIRB approved consent boilerplate [46]

Source URL: https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers

Links

[1] https://researchcompliance.stanford.edu/panels/hs/forms/training/citi
[2] https://researchcompliance.stanford.edu/panels/hs
[3] https://researchcompliance.stanford.edu/panels/hs/about/contacts
[4] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs
[5] https://researchcompliance.stanford.edu/panels/hs/forms/training/presentations
[6] https://stanfordmedicine.box.com/shared/static/b4o8sly1keffqz3vndke7nb56hsbsr7m.pdf
[7] https://researchcompliance.stanford.edu/panels/hs/common-rule
[8] https://stanfordmedicine.box.com/shared/static/8jrl22x1wd5vdh5pyklzn8mojs707oep.pdf
[9] http://spectrum.stanford.edu/researcher-resources/bioethics-romp
[10] http://spectrum.stanford.edu/romp-videos
[11] https://stanfordmedicine.box.com/shared/static/vqeuewr5axycjpu8h0wat77vqdpua9ru.pdf
[12] https://stanfordmedicine.box.com/shared/static/jm5gac2qyhz80glrmds8uas32fwn87ce.pdf
[13] https://eprotocol.stanford.edu
[14] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#reviewtype
[15] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates
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[20] https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/tips-medical
[21] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/medical#eprotocolreq
[22] https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf
[23] https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf#page=58
[24] https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf#page=62
[25] https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/nonmed-application
[26] https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/nonmed-eprotocol
[27] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/nonmedical#eprotocolreq
[28] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-076.html
[29] http://med.stanford.edu/rmg/contact.html
[30] https://osp.od.nih.gov/clinical-research/nih-policy-on-the-use-of-a-single-irb-for-multi-site-research-faqs-on-costs/
[31] http://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-003.html
[32] http://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-004.html
[33] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html
[34] https://www.quorumreview.com
[35] https://trialinnovationnetwork.org/elements/central-irb/
[36] https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm#5192
[37] https://grants.nih.gov/node/1272
[38] https://smartirb.org/
[39] https://eprotocol.stanford.edu/mydashboard
[40] https://stanfordmedicine.box.com/shared/static/dd8tug3acklexmndzmkzzo2s9jysjak3.pdf
[41] https://smartirb.org/sites/default/files/Relying_institution_checklist.pdf
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[43] https://stanfordmedicine.box.com/shared/static/ukpmjw3f4s96pecviki98ag2rziwlfjg.pdf
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[45] http://med.stanford.edu/content/dam/sm/ccto/sunet_id_resources/regulatory_documents/NCTN%20Guideline_Studies_Re
[46] https://stanfordmedicine.box.com/shared/static/miorq6i89ou80zhpun2wsbd6dzl730dc.doc