Stanford

Single IRB (sIRB)

Quick Links

- NIH Single IRB Policy
- Common Rule - Cooperative Research
- Relying on a Single IRB
- NCI CIRB

- Other webpages
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  - Training - what does the IRB Require? [2]
  - Forms and Processes [3]
  - Medical Research [4]
  - Nonmedical Research [5]

*** sIRB applications do not have a panel meeting date. The date assigned is for administrative purposes only. These applications are reviewed on a rolling basis, where the final reliance letter can be issued before, after, or on the assigned eProtocol date ***

Single IRB Mandates:

NIH Single IRB Policy ? Effective January 25th 2018.
Applies to all NIH funded multi-site studies conducting the same research at each site.

Cooperative Research ? Common Rule. ? Effective January 20th 2020.
Applies to federally supported, cooperative research ? i.e., studies that involve more than one institution.

Frequently Asked Questions (FAQs)

What is Single IRB (sIRB)?

One IRB of record (or Reviewing IRB), selected on a study-by-study basis, provides the regulatory and ethical review for all sites participating in a specific multisite study. Please refer to the sIRB SOP for other Single IRB related definitions.

What types of studies will Stanford agree to rely on Single IRB?s?

- Stanford will rely on external IRB for review when required per NIH Single IRB policy or Common Rule cooperative research provision.
- Stanford may consider reliance when the lead PI or the research consortium is mandating use of single IRB.
- Industry sponsored, research supported by other funding sources and unfunded research may be reviewed on case-by-case basis if reliance is required.

What is required for Stanford to rely on a Single IRB?

The Protocol Director (PD) is required to submit a sIRB eProtocol (eP) application [6] to request reliance on a sIRB. The following is required in the sIRB eProtocol application:

- Study Protocol
- Consent form (Any template can be used as long as Stanford required elements [7] are included)
- IRB Reliance document (check with the sIRB which agreement they would like to use)

Additional documents that may be required (if available)

- Federal Grant (when Stanford is the prime awardee)
- Investigator Brochure or FDA documentation
- Model consent template
- Single IRB approval
- Local Context document [8] (when requested by sIRB)

Who should I contact for more information about sIRB?

For questions about Single IRB please contact IRB Reliance Manager at singleirb@stanford.edu [9] or 650-736-9024.

What is a Reliance Agreement?

A reliance agreement, also called an IRB Authorization Agreement (IAA), is a document signed by two or more institutions engaged in human subjects research that permit one or more institutions to cede review to another IRB. This is generally initiated and provided by the sIRB.

Who signs the Reliance Agreement?

Stanford IRB has designated a signatory official that works with the IRB office on signing the reliance agreement. A reliance agreement is signed after Stanford receives and reviews the reliance request through eProtocol.

What is the SMART IRB Agreement?

SMART IRB (the Streamlined, Multisite, and Accelerated Resources for Trials IRB Reliance platform) Agreement is a Master IRB Reliance Agreement designed to harmonize and streamline the IRB review process for multisite studies and supports IRB reliance across the nation.

What options are available when Stanford is the Prime Awardee or the Lead site for an NIH funded multi-site study?

When Stanford is the Prime Awardee or the lead site for a federally supported project that is multi-site study or cooperative research requiring sIRB, researchers will need to consider the following reviewing IRBs to include in their proposal submitted to the Federal Department or Agency (e.g, NIH, NSF, DoD, VA, ED, DOE) for the use of an sIRB:

- Commercial IRB, e.g., Advarra IRB [10], WIRB [11]
- Trial Innovation Network Central IRB [12]
- 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 [13])

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 [14] (October 18, 2017) the sIRB of record does not have to be the IRB of the parent award.

What is expected from the Protocol Director when either relying on another IRB or serving as PI on a collaborative study?

Stanford expects the Protocol Director to follow additional responsibilities when relying on an external IRB as outlined at SMART IRB?s website [15], and to follow additional responsibilities when the Protocol Director is the sIRB lead PI (whether Stanford IRB, a commercial IRB, or another IRB is reviewing for an external site) outlined at SMART IRB?s website [16].

Single IRB Mandates:

NIH Funded Studies

NIH policy [17] on the Use of a Single Institutional Review Board for Multi-Site Research (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 [18] prior to submitting your proposal to NIH. NIH FAQs on sIRB costs [19].

- Guidance on Exceptions to the NIH Single IRB Policy (NOT-OD-18-003 [20])
- Guidance of Implementation of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-18-004 [21])
- 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 [22])
- Per NIH's Single IRB and Exception Process Webinar [14](October 18, 2017), the sIRB of record does not have to be the IRB of the parent award.

Common Rule - Cooperative Research

Cooperative Research funded under a Common Rule department or agency [23] must be reviewed in compliance with 45 CFR 46.114 (b [24])   (Final rule effective January 20, 2020).

- The revised Common Rule [25] (i.e., the 2018 Requirements) requires at 45 CFR 46.114 (b) (cooperative research [24]) that all institutions located in the United States that are engaged in cooperative research conducted or supported by a Common Rule department or agency [23] rely upon approval by a single IRB for the portion of the research that is conducted in the United States
- The Single IRB plan should be identified and included by the applicant within the grant application or the contract proposal.
- The proposed budget in the grant application/contract proposal should reflect all necessary Single IRB costs without an approved ?other exception?. Applicants should not assume that an exception will be granted when considering what Single IRB costs to include in the budget.

Cooperative Research - Supporting Docs

- Single IRB Exceptions:
  - November 21, 2019: Determination of Exception for Certain HHS-Conducted or -Supported Cooperative Research Activities Subject to the 2018 Requirements

[26]
- ○ [October 8, 2020: Exception to the Single IRB Review Requirements for Certain HHS-Conducted or - Supported Cooperative Research Activities Subject to the 2018 Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency](#) [27]
- NIH Guidance of Implementation of the Use of a Single Institutional Review Board (IRB) for Cooperative Research at 45 CFR 46.114 (b) ([NOT-HS-20-005](#) [28])
- Additional Guidance on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research ([NOT-OD-20-058](#) [29])

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](#) [30], 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 or required by the Revised Common Rule's Cooperative Research Provision (45 CFR 46.114). 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](#) [31] 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](#) [32] for more detailed information. See [here](#) [33] for additional Relying PI responsibilities.

[34]

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](#) [35]

More information

- [NCI CIRB Website](#) [36]
- [CCTO SoP for relying on a Central IRB](#) [37]

- Stanford University CIRB approved consent boilerplate [38]

Resources:

- SOP [32]
- Stanford sIRB Consent Requirements [7]
- Sample Medical Single IRB eProtocol form [39]
- Sample Non-Medical Single IRB eProtocol form [40]
- HIPAA [41]
- SMART IRB [30]
- sIRB Checklist [42]

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

Links

[1] https://researchcompliance.stanford.edu/panels/hs/about/contacts

[2] https://researchcompliance.stanford.edu/panels/hs/forms/training/citi

[3] https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers#forms_processes

[4] https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers#med_rsch

[5] https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers#nonmed_rsch

[6] https://eprotocol.stanford.edu/

[7] https://stanfordmedicine.box.com/shared/static/nrvyyq8mn4yqbnl2uvo61chk65awf313.pdf

[8] https://stanfordmedicine.box.com/shared/static/j8o5mw1xnlo0anddlwz0fmkwvsv0eb7o.pdf

[9] mailto:singleirb@stanford.edu

[10] https://www.advarra.com/

[11] https://www.wcgirb.com/

[12] https://trialinnovationnetwork.org/elements/central-irb/

[13] https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm#5192

[14] https://grants.nih.gov/node/1272

[15] http://smartirb.org/assets/files/Relying_institution_checklist.pdf

[16] http://smartirb.org/sites/default/files/PI_checklist.pdf

[17] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-076.html

[18] http://med.stanford.edu/rmg/contact.html

[19] https://osp.od.nih.gov/clinical-research/nih-policy-on-the-use-of-a-single-irb-for-multi-site-research-faqs-on-costs/

[20] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-003.html

[21] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-004.html

[22] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-109.html

[23] https://stanfordmedicine.box.com/shared/static/5e9j6o8km296w6uk9kvf878m7rg7c85j.docx

[24] https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-requirement/index.html

[25] https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=P

[26] https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/november-2019-exception-determination/index.html

[27] https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-exception-determinations/october-2020-exception-determination/index.html

[28] https://grants.nih.gov/grants/guide/notice-files/NOT-HS-20-005.html

[29] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-058.html

[30] https://smartirb.org/

[31] https://eprotocol.stanford.edu/mydashboard

[32] https://stanfordmedicine.box.com/shared/static/dd8tug3acklexmndzmkzzo2s9jysjak3.pdf

[33] https://smartirb.org/sites/default/files/Relying_institution_checklist.pdf

[34] https://smartirb.org

[35] https://stanfordmedicine.box.com/shared/static/ukpmjw3f4s96pecviki98ag2rziwlfjg.pdf

[36] https://www.ncicirb.org

[37]
http://med.stanford.edu/content/dam/sm/ccto/sunet_id_resources/regulatory_documents/NCTN%20Guideline_Studies_Re

[38] https://stanfordmedicine.box.com/shared/static/miorq6i89ou80zhpun2wsbd6dzl730dc.doc

[39] https://stanfordmedicine.box.com/shared/static/63kxdgg38l815heavd6ymoeremnw4pyq.pdf

[40] https://stanfordmedicine.box.com/shared/static/1fk3iyhz0as8hodq5cczcq9h78h57vo0.pdf

[41] https://stanfordmedicine.box.com/shared/static/8cxasnr3yupss0f5y24isk9s9xt04wua.doc

[42] https://stanfordmedicine.box.com/shared/static/093415ptsr80lb29x2o9sjog97gopbhm.docx