

Stanford

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[Home](#) > For Researchers

For Researchers

Quick Links

- [Training - what does the IRB require?](#) [1]
- [Do I need an IRB Submission?](#) (including [Human Subject Research determinations](#))
- [Forms and Processes](#)
- [Overview of the IRB Application](#) [2] (including definitions for Key Personnel)
- [eProtocol Training Videos](#) [3] **New!** not found or type unknown
- [Medical Research](#)
- [Non-Medical Research](#)
- [Single IRB \(sIRB\)](#) [4]
- [Common Rule - Cooperative Research](#) [5]
- [Relying on a Single IRB \(sIRB\)](#) [6]
- [NCI CIRB](#) [7]
- Other webpages
 - [What's New](#) [8] at the IRB
 - [IRB Contacts](#) [9]
 - [FAQs](#) [10]
 - [Presentations](#) [11] (education) provided to the research community
 - [Research at non-Stanford facilities](#) [12]: Can Stanford human subject, animal subject or human stem cell studies be conducted at non-Stanford facilities?

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](#) [13] page provides implementation information.

Training

- ["Let the IRB Staff Come to You!"](#) [14]: Researchers can arrange for 1-on-1 or group sessions
- For research participants, patients, and others interested in medical practice research - [Spectrum Education & Training](#) [15].

Do I need an IRB Submission?

- [Does My Project Need IRB Review?](#) [16] ()
- [\[17\]Determination of Human Subject Research Application](#) [17] () This form must be submitted in eProtocol as a Human Subjects Research (HSR) Determination.

To submit a 'Determination of Human Subject Research' form log into [eProtocol](#) [18], 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](#) [17] 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 Withdrawn applications DO meet the definition of human subjects research, and require that an IRB protocol be submitted and approved prior to any research activities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?](#) [19]

Forms and Processes

- [Forms & Consent Templates](#) [20]
- [Consent](#) [21]
- [Recruitment](#) [22]
- [Emergency Use of a Test Article](#) [23]

Medical Research

- [Medical Application Process](#) [24]
- [Special Considerations for Medical Application](#) [25]
- [Sample Medical eProtocol applications](#) [26]

Clinical trial documents: The following checklists are from the FDA E6 [Consolidated Guidance for Good Clinical Practice](#) [27]:

- [Checklist: Before the Clinical Phase of the Trial Commences](#) [28] (section 8.2) - Documents on file before the trial formally starts
- [Checklist: During the Clinical Conduct of the Trial](#) [29] (section 8.3) - Documents added to the files during the trial

Nonmedical Research

- [Non-Medical Application Process](#) [30]
- [Special Considerations for Non-Medical Applications](#) [31]
- [Sample Non-Medical eProtocol Applications](#) [32]
- [An Introduction to the Stanford IRB \(Social/Behavioral Research Focus\) \(37 minute video\)](#) [33]

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/forms/for-researchers/overview-of-the-irb-application>
- [3] <https://researchcompliance.stanford.edu/panels/hs/forms/training>
- [4] <https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/singleirb>
- [5] https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/singleirb#common_rule
- [6] https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/singleirb#ext_IRBs
- [7] https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/singleirb#nci_cirb
- [8] <https://researchcompliance.stanford.edu/panels/hs>
- [9] <https://researchcompliance.stanford.edu/panels/hs/about/contacts>
- [10] <https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs>
- [11] <https://researchcompliance.stanford.edu/panels/hs/forms/training/presentations>
- [12] <https://stanfordmedicine.box.com/shared/static/b4o8sly1keffqz3vndke7nb56hsbsr7m.pdf>
- [13] <https://researchcompliance.stanford.edu/panels/hs/common-rule>
- [14] <https://stanfordmedicine.box.com/shared/static/8jrl22x1wd5vdh5pyklzn8mojs707oep.pdf>
- [15] <https://med.stanford.edu/spectrum/education-and-training.html>
- [16] <https://stanfordmedicine.box.com/shared/static/vquewr5axycjpu8h0wat77vqdpua9ru.pdf>
- [17] <https://stanfordmedicine.box.com/shared/static/jm5gac2qyh80glrmds8uas32fwn87ce.pdf>
- [18] <https://eprotocol.stanford.edu>
- [19] <https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs#reviewtype>
- [20] <https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates>
- [21] <https://researchcompliance.stanford.edu/panels/hs/forms/consent>
- [22] <https://researchcompliance.stanford.edu/panels/hs/recruitment>
- [23] <https://researchcompliance.stanford.edu/panels/hs/forms/emergency>
- [24] <https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/med-application>
- [25] <https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/overview-of-the-irb-application#spec-med-app>
- [26] <https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/medical#eprotocolreq>
- [27] <https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf>
- [28] <https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf#page=58>
- [29] <https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf#page=62>
- [30] <https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/nonmed-application>
- [31] <https://researchcompliance.stanford.edu/panels/hs/forms/for-researchers/overview-of-the-irb-application#spec-nonmed-app>
- [32] <https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/nonmedical#eprotocolreq>
- [33] https://youtube.com/embed/TkAc_y7sYfc