

Stanford

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Basics

What is the eProtocol system?

[eProtocol](#) ^[9] is an online application used at Stanford to submit, review and approve research.

How do I use the eProtocol system?

See the webpage about [how to get started](#) ^[10] and [eProtocol FAQs](#) ^[11].

What is a protocol?

A protocol is a detailed plan for conducting research.

What does STANFORD (all caps) signify?

This denotes the five STANFORD affiliated organizations:

- Stanford University (SU)
- Stanford Hospital and Clinics (SHC)
- Lucile Packard Children's Hospital at Stanford (LPCH)
- Veterans Affairs Palo Alto Health Care System (VAPAHCS)
- Palo Alto Veterans Institute for Research (PAVIR)

Human Subjects Training

What training do I need?

Completion of human subject research training by all staff working on a research project (all investigators and other study personnel, including all persons who are responsible for the design, conduct, data analysis or reporting) is one of the requirements for protocol approval by the IRB.

See [CITI \(Tutorial\)](#) [12] for more information.

What is CITI?

Stanford provides access to the required training through the interactive online Collaborative IRB Training Initiative (CITI) Course: The Protection of Human Research Subjects.

How do I transfer training from another institution?

- **Transfer CITI training** completed at another institution:
 - Login to the [CITI website](#) [13] directly with your CITI or prior institution's login credentials.
 - Click on the link 'Associate With Another Institution' and choose Stanford.
 - Your completed modules will be recorded in Stanford's database.
 - If issues in transferring: Report the issues to [CITI support center](#) [14]
 - Once the transfer is completed successfully, your CITI trainings will reflect in your account when you login using SUNetID.
 - Stanford users without a SUNetID: Request a SUNetID from your Stanford department, before starting the transfer of CITI training.
- **Transfer non-CITI training** completed at another institution:
 - Contact **IRB Education** (650-724-7141) to see if your past training can be transferred. Generally, Stanford University will accept comparable Humans Subjects training from other institutions. You will need to provide the IRB your most recent training completion report.
 - When your training expires, register at CITI with Stanford University as your affiliate institution [to take the Refresher course](#) [15].
- See [CITI \(Tutorial\)](#) [16] for more information.

Why is my CITI training showing as incomplete in eProtocol?

If you have completed your training but it is not showing as completed in eProtocol, please contact the eProtocol helpdesk for assistance [here](#). [17]


Protocol Management

Before Submitting a Protocol

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-
- What qualifies as a pilot study?
- Quality Assessment & Quality Improvement (QA/QI) - different to research? [18]
- Can Stanford students conduct Human Subject research?
- How do I get information about Stanford students for my study?
- Who oversees student research?

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 - Data and Safety Monitoring Plan (DSMP) questions in eProtocol [22]
- See also eProtocol Help and FAQs [23]
- Consent
- My Academic Sponsor didn't get the financial disclosure email. What do I do?
- My name is not displaying correctly in eProtocol. What do I do? 
- Is any additional information needed for research involving the VA?

After Submitting a Protocol

- What happens after I submit my protocol?
- What is the status of my protocol?
- When can I expect to get IRB approval?
- Can I begin working on my protocol before approval?

After a Protocol is Approved

- Changes to approved protocols
- Events that must be reported to the IRB
- Continuing IRB Approval
- What happens when a protocol approaches its expiration date?
- If a protocol expires

Closing a protocol

- When and how to close a protocol
- When is a Final Report required?
- Record retention

Before Submitting a Protocol

Do I have to submit an application to the IRB?

Studies that meet the definition of Human Subject Research must be submitted to the IRB and must receive IRB approval before any study activities take place. This [chart](#) [24] may assist you in determining whether your study

meets the definition.

For additional information on certain student projects, pilot studies, oral history projects, or quality assessment/quality improvement projects, see:

- [Use of Human Subjects in Student Projects, Pilot Studies, Oral Histories and QA/QI Projects](#) [25]
- FAQs about [Quality Assessment & Quality Improvement \(QA/QI\)](#) [26]

You may also complete [this form](#) [27] and submit it through [eProtocol](#) [28] as a Human Subjects Research (HSR) Determination if you want the IRB to determine whether your activity constitutes human subject research.

IRB Review Fees

Initial and continuing review [Industry Sponsored Clinical Trials IRB Review Fees](#) [29].

What qualifies as a pilot study?

A pilot study is a preliminary investigation of the feasibility of the study which would not contribute to generalizable knowledge and therefore is not considered research. However, if the researcher plans to use the pilot data for research purposes, IRB review is required. More information on pilot studies is found [here](#) [25].

Can Stanford students conduct Human Subject research?

Stanford University supports a wide range of both undergraduate and graduate student research projects using human subjects ? from course-related research exercises to Ph.D. dissertation studies. More information is found [here](#) [25].

How do I get information about Stanford students for my study?

If you plan to request email addresses, or biographic, demographic or academic data on Stanford students from the Registrar's Office as part of your research, [email the Director of Institutional Research](#) [30] regarding the process to obtain these data before you submit your protocol to the IRB.

Who oversees student research?

Student protocols must have the Academic Sponsor review and fill out the [form for scientific and scholarly validity, and oversight](#) [31].

Submitting a Protocol (questions the PD should consider)

Should I submit a medical or non-medical protocol?

Medical Protocols	Conducted by personnel within, or conducted through, the School of Medicine (SOM), the Veterans Affairs Palo Alto Health Care System (VAPAHCS), the Palo Alto Veterans Institute for Research (PAVIR), or otherwise involving any medical procedure or use of personally identifiable health information are submitted on the Medical protocol application
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Social & Behavioral (Non-medical) Protocols	Human subjects research studies conducted by personnel within, or conducted through, Schools of Business, Education, Engineering, Humanities & Sciences, Law, and Psychology (except MRI studies) are submitted to the IRB on the Non-medical eProtocol application.
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Review Type: What is it and why do I need to know?

Before starting an eProtocol application, investigators must identify the appropriate Review Type. eProtocol then generates the appropriate form type for that review. There are six forms:

Select a Form Type below to create the eProtocol application for IRB review. Learn more about different form typee or contact IRBeducation@stanford.edu [32] or (650) 724-7141 if you have questions.	
Regular	For greater than minimal risk studies
Expedited	Minimal risk studies meeting specific criteria [33]
Exempt	Studies meeting specific criteria [34]
Chart Review	Chart review studies that only involve the use of data, documents, records
Single IRB (sIRB)	Studies where Stanford IRB is being asked to rely on an external IRB.
Human Subjects Research (HSR) Determination	Projects that don't clearly qualify as human subjects research. Include the HSR Determination form [35] in your submission.
Single Patient IND	Single patient treatment where the PD must obtain an IND from the FDA. Include FDA Form 3926 in your submission.
Humanitarian Use Device (HUD)	Treatment using a device with a Humanitarian Device Exemption [36] (HDE) issued by FDA.

Is there a guide to help me through the eProtocol system?

On the right side of your [eProtocol homepage](#) [9], there is a help section. Following are sections which may be useful to you:

Getting Started [37]	A Summary for New Users
eProtocol Training [38]	eProtocol Basics Video and Information on Group Training
eProtocol FAQs [23]	Getting Started, Managing Protocols, Troubleshooting

Consent

Documenting Consent

- [Consent Form Do's & Don'ts](#) [40] (a practical guide)

Can consent requirements be waived?

The IRB may approve a

? Waiver/Alteration of consent or a

? Waiver of Documentation (signature requirement)

if the research meets regulatory criteria.

What if there are non-English speaking participants?

Investigators are encouraged to recruit and include all segments of the community in research, including individuals whose primary language is not English. A general requirement for informed consent is that the 'information that is given to the subject or the representative shall be in a language understandable to the subject or the representative' [45 CFR 46.116 21; CFR 50.20].

Where can I get a consent form translated?

It is important that consent forms be translated accurately. Procedures for ensuring accurate translation should be described in the protocol application. For more information, contact Translation Services (Stanford Hospital and Clinics) at (650) 724-8735.

When can I use the short form consent process?

When all of the participants in a study (i.e., the target population) are anticipated to be non-English speaking, a full translated consent is strongly encouraged. Use of the [short form consent process](#) [41] and documents requires prior IRB approval.

Does the IRB provide translated short form consent documents?

There are [short form templates](#) [42] in many languages.

Does my research require an assent form?

Generally, a child 7 - 17 years old should sign an [assent form](#) [43].

My Academic Sponsor didn't get the financial interest disclosure email. What do I do?

Have them go to their [OPACS Dashboard](#) [44], locate the protocol, and click the red "Enter Response" button. They can answer the questions there.

My name is not displaying correctly in eProtocol. What do I do?

The user should go to [StanfordYou.stanford.edu](#), then click "Maintain your directory and AlertSU emergency contact information" and update the Preferred name. The name will then import to eProtocol.

Is any additional information needed for research involving the VA?

An additional set of questions is required for VA research. The [Required Questions - VA Research](#) [45] must be completed and attached in eProtocol.

After Submitting a Protocol

What happens after I submit my protocol?

Your protocol will be assigned to an IRB panel and meeting date. Be sure to watch for IRB comments. IRB staff may contact you by email or phone to obtain further information or to inform you of IRB questions/comments that require you to submit a response.

Please check your email daily for IRB comments during the month your protocol is being reviewed. Approval of your project may be delayed if responses to comments are not received promptly.

What is the status of my application?

eProtocol is the system of record and the My Dashboard page should be used to access information on protocol status:

- **Action Items** - Protocols needing action by the research team
- **In Process** - Protocols undergoing review by the IRB
- **Active Protocols** - Ongoing
- **Non-Active Protocols** - Closed or expired

When can I expect to get IRB approval?

- **Regular** - Generally, protocols are approved at the meeting date to which they are assigned.
- **Expedited, Exempt, Chart Review** - Generally, studies are reviewed in the order in which they are received. The actual approval date may be prior to the meeting date to which it is assigned.

Can I begin working on my protocol before I receive IRB approval?

NO. WAIT for IRB Approval. You may not begin your project until you have been notified of the IRB's approval. The IRB process takes about a month to review a new protocol, depending on the [review type](#). Be sure to allow time for the IRB to review and approve your protocol before you begin your research.

Under no circumstances should you interpret a lack of communication from the IRB as an approval. You can view your protocol status in the [eProtocol home page](#) [9].

After a Protocol is Approved

Protocol Directors must maintain appropriate study oversight, as described in [HRPP Policy Manual](#) [46] Ch. 15.3 Research Oversight.

Changes to approved protocols

All proposed changes to approved research must be prospectively reviewed and approved by the IRB, (except where necessary to eliminate apparent immediate hazards to subjects ? see [Events and Information that Require Prompt Reporting to the IRB](#) [47].)

Events that must be reported to the IRB

Certain events and circumstances (for non-Exempt human subject research) must be promptly reported to the IRB. See [Events and Information that Require Prompt Reporting to the IRB](#) [47].

Continuing IRB Approval

When applicable, the Protocol Director is responsible for ensuring that protocols are submitted for continuing review and approval by the IRB prior to the study's expiration date, and in sufficient time to ensure their non-interruption.

What happens when a protocol approaches its expiration date?

Studies with an expiration date must be reviewed by the IRB prior to the study's expiration. The expiration date is the last day that the protocol is approved (that is, the investigator may conduct research on the expiration date itself, but may not on the next day unless the IRB has approved renewal of the protocol following continuing review).

Researchers are alerted about an expiring protocol two months in advance by an eProtocol-generated notice, with a second reminder approximately one month later.

If no continuing review application has been received prior to an expiration date, an expiration notice is sent out within three business days of the protocol expiration; to keep the protocol active, a continuing review application must be submitted immediately.

If a protocol expires

Expired protocols appear in red type on the investigator's eProtocol Home Page under "Non-Active Protocols". They are not automatically closed due to non-response by the Protocol Director; once expired, the PD may ask the IRB staff to perform an "administrative close", or may contact the IRB to discuss options available.

Closing a protocol

When and how to close a protocol

Protocols should be closed in eProtocol when the study has been completed, or when the only remaining activity is analysis of de-identified data. The Protocol director is responsible for reporting the completion of the protocol to the IRB within 30 days.

A protocol is completed when all participants have been enrolled; all participants have completed all research-related interventions, including any protocol required follow-up; all analysis of identifiable data is completed; and all funding and contracting issues have been completed/cleared. See the [HIPAA and PHI guidance](#) [48] for more information on de-identification.

Protocols are closed via eProtocol, either by submitting a Final Report to the IRB (required for certain protocols - see below), or by changing the protocol status in eProtocol (see [eProtocol instructions](#) [49].)

When is a Final Report required?

A Final Report must be submitted to the IRB for:

Final Reports are **required** for:

- Research that was subject to regular review and that enrolled participants,

Final Reports are **not required** for:

? Research subject to expedited* or exempt review, or

? Research projects subject to regular review that never started or never enrolled participants at STANFORD.

The Final Report should be submitted to the IRB within 30 days of the study completion.

*All Expedited FDA-regulated protocols must be closed by the Protocol Director.

Record retention

All data, **including all signed consent form documents**, must be retained for a **minimum of three years** past the completion of the research. Additional requirements may be imposed by the funding agency, your department, or other entities (e.g. 6 years for studies conducted under HIPAA). (See also Research Policy Handbook [RPH](#) [50]1.9 [51]- [50][Retention of and Access to Research Data](#) [51])

Genomic Data Sharing

See:

- Stanford HRPP guidance [NIH Genomic Data Sharing for NIH Grant Submission](#) [52]
- [RMG website](#) [53]
- genetics v. genomics - see [Lay Language Glossary](#) [54] definitions
- [NIH Genomic Data Sharing \(GDS\)](#) [55]

How do I obtain Institutional Certification so I can submit data to an NIH-supported genomic data repository (e.g., dbGaP)?

1. Complete and sign an [Extramural Institutional Certification](#) [56].
2. Submit the following to the [IRB](#) [57]:
3. Once the IRB has confirmed the data can be submitted to an NIH-supported genomic data repository. The IRB will forward the Institutional Certification form signed by the Investigator to the RPM for the Authorized Institutional Official signature.
 - Each unique consent form
 - A completed corresponding [NIH Genomic Data Sharing \(GDS\) Consent Checklist](#) [58] for each consent form
 - Institutional certification form signed by the Investigator

What should I do if the initial consent forms are not consistent with submission of data to the NIH Repository, or if there was no informed consent obtained?

- For data from specimens collected before 1/25/2015, the IRB will assess whether the data submission is consistent with the informed consent given by the participant. NIH will accept data derived from de-identified cell lines or clinical specimens lacking consent for research that were created or collected before 1/25/15.
- For studies initiated after 1/25/15, NIH expects researchers to obtain participants' consent for their data to be shared broadly for future research.
- For studies that prohibit sharing by using statements such as "Your data will never be shared outside of

Stanford, re-consenting may be possible. Any plan to re-consent should be submitted to the IRB as a modification to the protocol along with the modified consent form prior to implementation.

- See [Related Non-Stanford Sites](#) [59] for additional NIH resources.

Research involving cadavers or deceased individuals

Does the IRB require a protocol for research involving cadavers or deceased individuals?

Generally speaking, research involving cadavers or deceased individuals does not meet the definition of human subjects research. However, there may be circumstances where IRB oversight is needed, such as when obtaining CA State-produced death records or indices, or tissues/samples prospectively collected from individuals who were/are living at the time of sample collection. If in doubt, contact [IRB Education](#) [60].

Does the IRB need to review research involving protected health information (PHI) about deceased individuals?

HIPAA protections extend beyond an individual's death. Please work with the [Privacy Office](#) [61] to determine how best to obtain authorization to use and disclose PHI from deceased individuals.

Certificate of Confidentiality (CoC)?

What is a Certificate of Confidentiality (CoC)?

CoCs protect the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents or in a few other specific situations. Effective October 1, 2017, all ongoing or new research funded by NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically issued a CoC through a term and condition of award. Other federal agencies will continue to issue CoCs to researchers they fund via [an application process](#) [62]. Research that is not federally funded can apply for a CoC to NIH or the FDA as appropriate. For more information on the NIH Policy: <https://humansubjects.nih.gov/coc/index> [63]

If part of my cohort was recruited prior to issuance of the Certificate do I need to re-consent them?

Neither the NIH Policy on Certificates of Confidentiality nor subsection 301(d) expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted and informed of the Certificate. However, IRBs may determine whether it is appropriate to inform participants. [Go to the NIH CoC Kiosk for more FAQs](#) [64]

European Union General Data Protection Regulation (GDPR)

What is GDPR?

Effective May 25, 2018, Stanford University is required to comply with the European Union General Data Protection Regulation (GDPR) which regulates the collection, processing, storage, transfer, and protection of personal information, including data collected for research. The GDPR is a comprehensive privacy law that governs any entity that collects or processes the personal data of any citizen of the member states of the European Economic Area (<https://www.tripsavvy.com/countries-that-are-eea-countries-1626682> [65]).

What do researchers need to do?

For research that includes human subjects, language for the consent will be provided to you during IRB review. [The language](#) [66] will inform participants about their study data regulated under the GDPR.

Find out more:

If you have specific questions about GDPR, please contact the Privacy Office at privacy@stanford.edu [67] or 650-725-1828. You can also find additional information on GDPR at <https://privacy.stanford.edu/gdpr/training> [68] and [DoResearch](#) [69].

Expanded Access, Emergency Use, Humanitarian Use (HUD)

Expanded Access

- [What is Expanded Access?](#)
 - [What is Compassionate Use?](#)
 - [Does Expanded Access require IRB approval?](#)
 - [Does Expanded Access require FDA approval?](#)
- [What are Expanded Access reporting requirements to the FDA?](#)

What is Expanded Access?

Expanded Access is when investigational drugs, biologics, or devices are made available, under certain circumstances, to treat patient(s) with a serious disease or condition who cannot participate in a clinical trial. Expanded Access can be permitted by the FDA for individuals, intermediate size groups or widespread treatment, each under specific criteria. [[21 CFR 312.300 \(Subpart I\)](#)] [70]

See: [Expanded Access Brochure](#) [71]; [HRPP Policy Manual](#) [46] Chapter 5.8

[get info](#) [72]

What is Compassionate Use?

?Compassionate Use? has commonly been used to refer to expanded access. The term ?Compassionate Use? is used in the [FDA guidance](#) [73] for Single Patient/Small Group Access to a device.

[Get more info](#) [72]

Does Expanded Access require IRB approval?

All Expanded Access, except Emergency Use (see [GUI-6](#) [74]), requires prior IRB review and approval.

[Get more info](#) [72]

Does Expanded Access require FDA approval?

DRUGS

Prior approval from the FDA is required (either a new IND or a protocol amendment to an existing IND).

DEVICES

The sponsor should submit an IDE supplement to the FDA requesting approval for a protocol deviation.

[Get more info](#) [72]

What are Expanded Access reporting requirements to the FDA?

DRUGS

Submit IND safety reports promptly, and annual reports if the protocol continues for one year or longer.

DEVICES

Sponsor must submit semi-annual progress reports to the FDA until the filing of a marketing application. After filing, progress reports must be submitted annually [21 CFR 812.150(b)(5) ^[75]].

[Get more info](#) ^[72]

Emergency Use

- [What is Emergency Use?](#)
- [Is permission needed for Emergency Use?](#)
[What are Emergency Use reporting requirements?](#)

What is Emergency Use?

Use of an investigational article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d) ^[76]].

[Get more info](#) ^[77]

Is permission needed for Emergency Use?

Contact sponsor to obtain permission to use and obtain test article.

Contact FDA for DRUGS ? Emergency use may be requested by telephone, facsimile, or other means of electronic communications.

DEVICES ? No prior approval from FDA is required for shipment or emergency use of investigational devices.

IRB: Emergency Use is exempt from prior IRB review and approval, provided it is reported to the IRB within 5 working days after the use. Contact IRB if you have any questions.

[Get more info](#) ^[77]

What are Emergency Use reporting requirements?

IRB:

Must be reported to the IRB within 5 working days after the use:

[Emergency Use of a Test Article ? Notification to the IRB](#) ^[78]

FDA:

Drugs: Physician or sponsor must submit a new IND, or amendment to an existing IND, within 15 working days of FDA's authorization of the use. Clearly mark "Emergency IND" on top of Form 1571.

Devices with IDE: Sponsor is responsible to report the use after receiving sufficient information from the physician.

Devices with no IDE: Physician must report the use within 5 working days.

See also [HRPP Policy Manual](#) ^[46] Chapter 5.9

[Get more info](#) ^[77]

Humanitarian Use (HUD)

What is a Humanitarian Use Device (HUD)?

A medical device intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.

See also [HRPP Policy Manual](#) [46] Chapter 5.10

[Get more info](#) [79]

Source URL: <https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates/faqs>

Links

- [1] http://researchcompliance.stanford.edu/panels/hs/forms/researchers#single_irb
- [2] <https://researchcompliance.stanford.edu/rco/meetings>
- [3] <http://researchcompliance.stanford.edu/rco/eprotocol/docs/RCOFAQOffsiteResearch.pdf>
- [4] https://researchcompliance.stanford.edu/panels/hs/forms/researchers#single_irb
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- [25] <http://doresearch.stanford.edu/policies/research-policy-handbook/human-subjects-and-stem-cells-research/use-human-subjects-student>
- [26] <http://stanfordmedicine.box.com/shared/static/nvuzhf3pjqsrx4890jax7uwbglbxc4.pdf>
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- [30] <mailto:cjpotter@stanford.edu>
- [31] <https://stanfordmedicine.box.com/shared/static/j6di978rz4t46rsh60hxzc94i2rzygg4.doc>
- [32] <mailto:IRBeducation@stanford.edu>
- [33] <http://stanfordmedicine.box.com/shared/static/uzm5fctlrur2nm4b2zvmra21mluh0rt5.pdf>

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