IRB Medical Application Process

General Information

Timeframe for Filling out an Application
Be prepared to spend a few hours on the protocol. You don’t need to write the entire application in one sitting. You can complete some sections and then save and exit the system, and come back to the same protocol to finish filling it out without having to start a new protocol application. If your protocol requires a consent form(s), please follow the consent form templates [1] provided.

Submission Deadlines
Medical protocols are assigned for review on a first-come, first-served basis. The protocol must be complete to be assigned to a Panel.

If your project is complicated or involves sensitive information, please submit your protocol well in advance of your desired start date, to allow time for additional discussion or review.

Convened IRB Meetings
Stanford has 5 medical IRBs with monthly convened meetings, so there are IRB meetings nearly every week in most months. Notable exceptions are November and December, when IRB meetings are moved forward to accommodate Stanford’s Thanksgiving and annual holiday break (see the schedule of meeting dates and submission deadlines [2]).

If your protocol needs to be presented at a convened meeting, the protocol review takes place in the weeks leading up to the meeting. All IRB concerns should be addressed by the time the proposal is presented to the Panel. Investigators are NOT asked to attend the meetings to present their protocols.

How long does IRB review take?
Protocols are reviewed by the IRB staff and IRB members. Comments and questions are sent to the Protocol Director to be addressed prior to a convened meeting, and there may be multiple cycles of comments and responses.

Under no circumstances may research begin until the Protocol Director has received a Notice of Certification (for
Exempt protocols) or an IRB Approval Letter (for Expedited or Regular protocols). Once your protocol has been approved, you will receive an email instructing you how to access your Certification or Approval Letter online.

**Regular Review**
All Regular protocols must be presented, discussed and voted on at a convened meeting of the IRB. This process generally takes 4-6 weeks.

**Expedited Review**
Federal regulations allow for some protocols [3] that involve no greater than minimal risk to be reviewed by a single IRB member and to be approved when that member has recommended approval. These protocols are assigned to a target date on an Expedited IRB, but approval can take place as soon as the protocol is reviewed and approved, without needing to wait for a convened meeting or for the target date. This type of review normally takes 2-4 weeks.

**Other Issues Related to Length of Review**
You should always plan ahead in judging when to submit your protocol application to the IRB. However, on occasion there may be extenuating circumstances, such as just-in-time funding or the emergent need to treat a participant, which require speedier action on the part of the IRB. Call or email the IRB to let them know when this is the case. The IRB will do what it can to accommodate reasonable requests.

**Protocol Format**
Your protocol should be written for the lay person. The IRB members represent a variety of disciplines. This means that some reviewers will not be as familiar with the terminology as you are, so please use language that a lay person would understand.

**Academic Sponsor**
If you are a student (medical student, post-doc or fellow), you must list an academic sponsor on the protocol. Please note that protocols cannot be approved without academic sponsor approval (a form will be provided for this purpose during the review process).

**Emergency Use of a Test Article**
If the need arises to treat a patient in a life-threatening situation with an investigational drug or device, and there is no time to obtain IRB approval, call the IRB or refer to this guidance [4].

**Protocol Submission**

Before a research protocol can be submitted to the IRB, investigators must first identify the appropriate form type (Medical or Non-Medical) and the appropriate review type [11], i.e., whether the protocol qualifies for Exempt, Expedited or Regular review.

These decisions, in turn, determine which application you will complete. To assist in preparing for an eProtocol submission Sample eProtocol Applications [12] are available.

**Protocol Status and Historical Information**
The eProtocol system should be accessed for information on current protocols. Some historical information about events prior to 3/8/08 is available from a previous database system. Contact us [13] if needed.
Sponsor-Investigator Research

Stanford IRB policies (HRPP Policy Chapter 5.6 [14]) require additional oversight of research when the Stanford (SU, SHC, LPCH, VA) investigator holds the IND or IDE. An investigator who holds an IND or IDE must perform the FDA mandated responsibilities for both an investigator and a sponsor, including communicating information to the FDA about the study.

Prior to approving a protocol that involves a sponsor-investigator, the IRB must be satisfied that the sponsor-investigator is knowledgeable about his/her responsibilities and has adequate policies and procedures in place to comply with the FDA regulatory requirements. For more information on the FDA and IRB requirements see these guidance documents for holders of the IDE [15] or IND [16].

Possible Registration Requirements

ClinicalTrials.gov

All clinical trials that meet the HHS regulations [17] and NIH policy [18] must register at ClinicalTrials.gov [19].


Questions about registrations?

For non-cancer research, contact the Spectrum Clinical Trials Disclosure Team [21]

For cancer research, contact the Cancer Clinical Trials Office [22] (CCTO). For assistance on study registration, email Sarah Pelta [22] or call 650-724-0513.

ICMJE (International Committee of Medical Journal Editors)

Policies of the ICMJE [23] require registration of any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

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

Links
[8] https://www.google.com/chrome/
[12] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates#eprotocolreq