How do I open a CIRB protocol?

- Complete the *Annual PI Worksheet* in *IRBManager* (if not completed previously.) *Click here for instructions.*
- Prepare the Informed Consent Form with Stanford template language:
  - Approval Date = the date listed on the Study-Specific Worksheet approval letter that stating approval by the CIRB.
  - Expiration Date = CIRB's Expiration Date.
  - Thereafter, all Approval and Expiration Dates will match CIRB dates.
- Complete the *Study-Specific Worksheet*; submit it to CIRB.
- Study is opened at Stanford when CIRB sends an approval letter via email.

When am I required to open a protocol with Stanford?

- If the study enrolls prisoners, or if a subject enrolled at Stanford becomes a prisoner while participating in a CIRB study, you will need to complete a new study application within eProtocol to continue this subject's participation in the study.
- An eProtocol application must be submitted if the CIRB study requires a Waiver of HIPAA Authorization.
- If you intend to collaborate with the VA, you will need a full Stanford protocol.

How do I renew a CIRB protocol?

- Submit renewal documents to the appropriate oncology group, as you would normally.
- When CIRB posts the renewal documents, update the Approval and Expiration Dates in the Informed Consent Form template to match the CIRB dates.

Note: CIRB has already renewed the protocol based on information received from initiating oncology group.

How do I handle revisions, modifications, and local reports?

- **If the revision originates from the oncology group (i.e. COG) and is posted on the CIRB website:**
  This means it has already been approved by the CIRB; update all local documents, make the changes in your regulatory binder, including changes to practice and protocol, and proceed under the revised protocol.
- **If the revision requires changes to the PD**
  - The PD must login to *IRBManager* (NCI goes in the Client box),
    - select *Start xForm*
      - select *Study-Specific Worksheet About Local Context*
        - Select *Change of PI* radio button as the reason for submission

- **If the revision requires changes to the research personnel:**
  - **Complete this form:** https://www.ncicirb.org/Personnel_SignatoryInstitution.doc
    - Email the completed form to cirb-staff@lists.stanford.edu
      - The Stanford IRB will submit the form to NCI CIRB Help Desk <NCICIRBcontact@emmes.com>
        - The Stanford IRB and the research staff will receive a notification email of completion from NCI CIRB Help Desk

- **If the revision requires changes to the Informed Consent Form:**
  Informed Consent Document(s) are considered approved for use once you have updated appropriately per amendment. The Approval Date should coincide with the Approval Date on the revision. This becomes your most current ICF.
  Note: Expiration Date does *not* change for revisions (it is set when new, and changes only for annual renewals.)

- **For any locally-occurring potential unanticipated problems and/or serious or continuing noncompliance (UP/SCN):**
  - The PD must login to *IRBManager* (NCI goes in the Client box)
    - select Start xForm
      - select Unanticipated Problem and/or Noncompliance Form

- **Creation of local advertisements or flyers:**
  - Any local recruitment tools should be submitted to CIRB for approval before use.

What about other documents, like Memos regarding drug shortages or Letters to Families?

A good rule of thumb: If it's posted on the website, CIRB has reviewed and approved it. You do *not* need to submit it to the IRB.

How do I close a CIRB study here at Stanford?

  - The PD must login to *IRBManager* (NCI goes in the Client box)
    - select Start xForm
      - select Study Closure or Transfer of Study Review Resp.

Instructions for *IRBManager*

For information about NCI CIRB online worksheet submissions:
Instruction Manual for Worksheet Completion in *IRBManager*