Life Cycle of an NCI CIRB protocol at Stanford under the New Independent Model

**Oncology Group (OG)**
- Scientific review at CTEP takes place before protocol is sent to CIRB
- Protocol submitted to CIRB
- Revisions, Renewals submitted to CIRB
- AEs, SAEs submitted to DSMB, which sends reports to CIRB
- Performs triennial audit of each site

**CIRB**
- Reviews and approves OG protocol
- Publishes New protocols, Revisions, Renewals on CIRB website
- CIRB reviews/approves Study-Specific Worksheet; notifies researcher & local IRB of acceptance
- Confirms local site closure to Researcher and to local IRB

**Researcher**
- Before Protocol Creation
  - Completes Annual PI Worksheets (ongoing)

**After Protocol Published on CIRB Website**
- Submits application to Clinical Research Group (CRG) at Stanford Cancer Institute (SCI)
- Upon approval by SCI, downloads protocol
- Completes consent form template with study specifics
- Submits Study-Specific Worksheet to CIRB

**Study Underway**
- Enrollment starts
- AEs, SAEs reported to OG
- Local possible UPs; serious/continuing noncompliance sent to CIRB (cc: local IRB)
- Submits any local modifications (e.g., flyers) to CIRB
- Personnel revisions sent to local IRB

**Local IRB**
- Complete Annual Institutional Worksheets (ongoing)
- Receives Study Worksheet Acceptance from CIRB
- Receives Closure Forms from CIRB
- Maintains list of current active CIRB protocols
- Assist with audit preparation (major deficiencies are submitted to CIRB)
- Periodic consent form review

**CrG-SCI**
- Reviews & approves application

**Current CIRB-approved Consent on secure website or “Oncore”**

**Current Active CIRB Protocols**

**Local IRB cannot rely on CIRB if:**
- Participant becomes prisoner & remains in study
- Waiver of HIPAA Authorization is required

**Stanford University HRPP**

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Research Compliance Office