Compliance Monitoring & Policies

Periodic compliance reviews are performed to evaluate adherence to applicable regulations, laws and policies, and to verify that research is conducted and documented in accordance with IRB-approved protocols.

- **Planned Compliance Reviews:** The CQI Team [1]schedules periodic reviews of IRB's processes, procedures, and records, as well as researchers? activities and records, e.g. consent forms and regulatory documents.
- **For-Cause Reviews:** The IRB or the RCO Director may direct the CQI Team [1] or other designees to conduct a review in response to a particular concern.
- **Stanford Sponsor-Investigator Research (SIR) [2]:** The IRB conducts an annual regulatory and informed consent form compliance review.

Other activities in this area include:

- **External Auditing Results:** The CQI Team [1] receives and analyzes audit/inspection reports from external entities and from Stanford's Internal Audit Department.
- **Tools for Researchers:** The CQI Team [1] develops checklists, templates and tools to assist researchers to comply with applicable requirements and self-assessments.
- **Communication within the HRPP:** The CQI Team [1] meets regularly with the HRPP Organizations to discuss the application of new or existing regulation and policy, relevant compliance issues and to learn about the relevant activities of other organizations within HRPP.

Links
[1] https://researchcompliance.stanford.edu/panels/hs/cqi-contacts
[2] https://stanfordmedicine.box.com/shared/static/s3rx27hoc363gclja1wm2hvzweh1p5h7.pdf