*STANFORD measures and improves, when necessary, compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization also measures and improves, when necessary, the quality, effectiveness, and efficiency of the Human Research Protection Program. (**AAHRPP Standard I-5**)*
*The Organization conducts audits or surveys or uses other methods to assess compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance. The Organization makes improvements to increase compliance, when necessary. (**Element I.5.A**)*
*The Organization conducts audits or surveys or uses other methods to assess the quality, efficiency, and effectiveness of the Human Research Protection Program. The Organization identifies strengths and weaknesses of the Human Research Protection Program and makes improvements, when necessary, to increase the quality, efficiency, and effectiveness of the program. (**Element I.5.B**)*

CQI ACTIVITIES

The Continuous Quality Improvement program evaluates the effectiveness of the STANFORD[1] HRPP in assuring the rights and welfare of human subjects and compliance with applicable laws, and identifies areas of opportunities for improvement and education in line with AAHRPP accreditation standards. Activities include:

a) Conducting routine and ad-hoc reviews to monitor compliance with HRPP policies and procedures,

b) Responding to and tracking questions, complaints and non-compliance to identify areas for improvement,

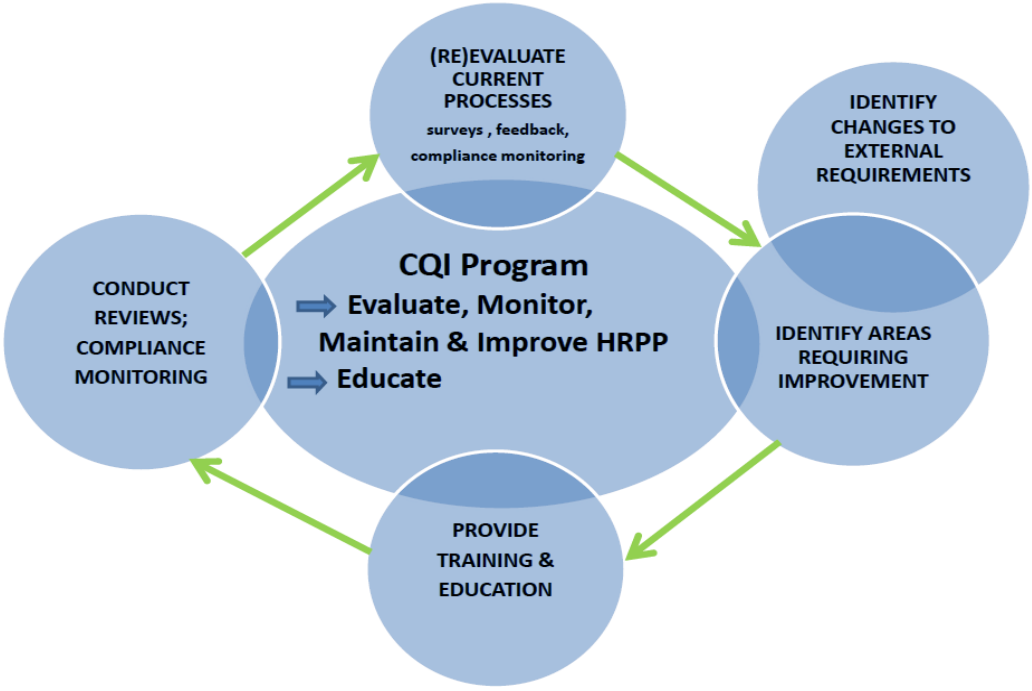
c) Conducting surveys to evaluate effectiveness of various aspects of the STANFORD HRPP, and identify improvements to HRPP policies, procedures and guidelines,

d) Analyzing metrics of the IRB operations, as input to RCO management decisions, and to identify areas for improvement,

e) Providing education or assistance to IRB Members, staff, investigators and other members of STANFORD research community in areas pertinent to human subjects protections,

Before the beginning of the new IRB Year (October 1), based on input from the RCO Senior Management and IRB members, the HRPP Associate Director and Sr. HRPP Lead develop the Annual Education and Monitoring Plan for the coming year. The plan incorporates routine monitoring activities and ad-hoc monitoring activities as required to achieve the specific objectives for compliance improvement that have been identified. The plan is adjusted throughout the year to address new input received from the CQI monitoring and evaluation activities described above, and to respond to changes in external requirements. The plan is approved by the RCO Director and Deputy Director.

[1] STANFORD refers to the five affiliated STANFORD 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), and Palo Alto Institute for Research and Education (PAIRE).



(A) Conduct Reviews - Compliance Monitoring

Periodic compliance reviews and for-cause reviews are used to evaluate adherence to applicable federal regulations, state and local laws, and STANFORD policies and procedures, and ensure that research is conducted in accordance with the IRB approved protocols. For example:

- **Periodic Compliance Reviews:**
  - Examinations of executed informed consent forms or observations of the informed consent process;
  - Reviews of IRB meeting minutes;
  - Detailed examinations of protocol files.
- **External Auditing Results:**
  - Review of audit/inspection reports from external agencies (e.g., FDA) and STANFORD HRPP component organizations (e.g., Internal Audit, Cancer Center DSMC, VAPAHCS) as applicable.
  - Participation in opening and closing sessions of external audits (e.g., FDA) of research conducted within the HRPP.
- **For-Cause Reviews:**

  The RCO Director or HRPP Associate Director may request a review in response to a particular concern expressed by the IRB or other parties. Concerns that may prompt a for-cause review include but are not limited to:
  - Identified weaknesses from periodic compliance reviews;
  - Reported complaints or concerns;
  - Reports of serious or continuing non-compliance; and
  - Results of audits or monitoring conducted by STANFORD organizations.

(B) Evaluate Current Practices and Processes

- **Tracking feedback:** Comments, questions and issues received from STANFORD investigators and participants to identify areas for potential improvement in the effectiveness of HRPP policies and procedures and for ensuring human subjects protections are tracked from a variety of sources, including:
  - Telephone calls and email communications received from the research community
  - Surveys of the research community and IRB members
  - Follow-up on questions or complaints received from participants or the research community
- **IRB Performance Metrics:** These are produced by analyzing reports from the eProtocol system, and include measurements of processing times and activity volumes by IRB, by protocol event type, in detail and cumulatively.
- **Reporting the Results of Compliance Monitoring and Feedback Tracking:** Metrics, compliance monitoring, and the results of feedback activities are documented and reported to the RCO Director and Senior Management, and to the IRB, Institutional Officials and other units within STANFORD as appropriate. These results, supplemented by Internal Audit results when available, provide a quantitative and qualitative measurement of compliance with the HRPP and applicable regulations.

(C) HRPP Update and Process Improvement

Based on analysis of regulatory requirements, reviews, and feedback received from the communities served by the IRB, the HRPP Associate Director and the Sr. HRPP Lead develop and recommend action plans to correct issues and provide education and outreach to promote effective improvement. Input is sought from the HRPP component organizations to discuss relevant issues and develop appropriate action plans:

- Cancer Clinical Trials Office (CCTO)
- Spectrum (The Stanford Center for Clinical and Translational Education and Research)
- Office of Sponsored Research
- VAPAHCS and PAIRE

Implementation of the approved action plans may lead to significant changes to the HRPP:

- Changes to HRPP policies and procedures;
- Changes to the eProtocol application system;
- Design and delivery of targeted education for IRB Members, Staff and the research community.

These actions are monitored to ensure effectiveness and consistency. This leads to the continuous improvement of the HRPP and the protection of human subject research participants.

(D) Training and Education of IRB members, IRB staff, and the research community regarding human research protections.

New IRB members and IRB staff receive orientation to the STANFORD HRPP. All IRB members and IRB staff receive regular, ongoing training and continuing education; the Training Specialist announces opportunities for continuing education in human research protections on a regular basis.

Before the beginning of a new IRB Year (October 1), the HRPP Associate Director and the Sr. HRPP Lead propose education plans for the upcoming year to the RCO Senior Management. The plan

incorporates input from IRB members, IRB staff, investigators, and from CQI monitoring and evaluation activities. Trends in research at STANFORD are considered, and new federal, state or local regulations (or published guidances) are integrated. The plans are adjusted as necessary to address areas for improvement that are identified from the results of compliance monitoring activities (e.g., internal and external audits) and feedback received from participants and the research community. The plan is approved by the RCO Director and Deputy Director.