Chapter 20

Quality Improvement Program

The stated mission and purpose of the Human Research Protection Program is to promote and assure the ethical conduct of research and the safety of participants in that process. The Human Research Protection Program (HRPP) has an established quality improvement program (QIP) that assesses ongoing compliance with the federal and state laws, organizational policies, and ethical principles. The Quality Improvement Plan is evaluated annually, and specific measures/metrics are evaluated based on trends and identified needs. The specific measures will assess effectiveness, efficiency, and quality of the HRPP.

1. **Purpose:**
   The purpose of the Quality Improvement Program for the HRPP is twofold:
   a. To provide a systematic, internal process that will increase compliance with federal, state, and institutional requirements and promote human participant protections through the ethical conduct of research and,
   b. To identify and develop education and resources in support of the research community and research participants.

2. **Objective:**
   The objective of the HRPP quality improvement program is to measure and improve the effectiveness, quality, and compliance of the program. The scope of the program encompasses all research done under the auspices of the Prisma Health Institutional Review Board.

3. **Scope of Reviews for Quality Improvement:**
   Processes and studies selected for review will be random or based on aggregate findings from prior period reviews and reports. Specific issues of identified non-compliance or risks we will be managed through a "for-cause" audit process defined in Chapter 21 of this document.
   Areas of focus may include:
   a. Higher risk studies.
   b. Investigator-initiated protocols.
   c. Studies that include vulnerable populations as defined by regulation and/or by IRB committee determination of situational vulnerability.
   d. Potential or identified conflict of interest that impact subject selection and consent.
   e. Data integrity, privacy, and confidentiality.
   f. IRB office compliance with administrative review requirements, committee function, and management.
   g. Committee member documentation of review processes and effectiveness of review processes.

4. **Types of Quality Reviews to assess Investigator Compliance**
   a. *Random Scheduled Review* - Random reviews are conducted post-approval. The focus of the review includes role and responsibilities of research team members, regulatory compliance with consent form elements, consent form process, protocol compliance, data collection and security, and other relevant aspects of the study. These reviews may, when necessary, be conducted remotely.
   b. *Directed Review* - Directed reviews are conducted when trends in specific

issues are identified by IRB staff, IRB committees, research staff, investigators, or participants. A directed review will be conducted by the HRPP Compliance Coordinator or designee determined by the HRPP Director. Follow-up reviews will be scheduled to assure ongoing compliance with requirements and effective resolution of identified issues.

c. *Informed Consent Review* - Review and observation of the consent process is conducted to assure that the consent process meets the intent of consent regulation and ethical requirements of the process. This type of review includes observation of the consent process, verification of the qualifications of the consenting individual, confirmation that the potential participant is provided a copy of the consent form and provided an opportunity have questions answered, the participant demonstrates an understanding of the information provided and their responsibilities as part of the study.
d. *Quarterly Review to Assess Compliance with Regulatory Requirements and Policy* - Administrative assessment reviews are conducted by the HRPP Compliance Coordinator and are initiated as part of a quarterly planned review, identification of issues of non-compliance with regulation or policy, or to assess the effectiveness and/or efficiency of new or modified processes/policies or compliance with changes in existing regulation.

   Assessment may also be conducted at the direction of the HRPP director to assist with evaluation of performance and training needs of HRPP staff, or committee members. The results of these reviews are shared with the HRPP Director, Vice President for Research Administration and Compliance. Findings of these reviews will be shared with HRPP staff, study teams, investigators, committee chairs, and members when relevant to their role in the protection of human subjects in research.

   1. <u>Examples of areas/issues where a period review of performance may be conducted:</u>
      a. IRB member performance
      b. Timeliness of staff responses to investigator or study staff
      c. Assessment of outreach activities and resources available to investigators and research staff
      d. Modifications required on initial submission and volume of "not ready for review" submissions and omissions and errors that drive this designation
      e. Appropriate consideration, documentation, and assessment of processes and plans in place for protecting vulnerable or potentially vulnerable populations.
      f. Timeliness of continuing review of approved research and documentation of determination for requiring continuing review when no longer required by regulation
      g. Documentation for and approval of waivers of consent and/or alteration of elements of informed consent
      h. Inclusion of all required elements of informed consent as required by regulation and determinations of the IRB committee
      i. Appropriate considerations for data management and safety management
      j. Completeness of IRB committee meeting minutes and determination letters
      k. Quality and effectiveness of the HRPP and IRB systems

5. Assessment of Outreach Activities

Annually, the IRB Chairs, the HRPP Director, and selected investigators and research staff will conduct a review of the HRPP and IRB community outreach efforts. Assessment may include interviews, surveys, focus groups, and written evaluation of outreach activity. Prisma Health resources, to include the Patient Engagement Studio (in partnership with the University of South Carolina Medical School, Greenville Campus), Diversity and Inclusion team and Resource Groups and Community Outreach programs. These activities to enhance patient/community engagement in research development will be incorporated into the annual assessment and plan.

6. Annual Assessment and Plan

Annually, at the beginning of the fiscal year (October), HRPP leadership and the HRPP compliance coordinator will meet to establish the QI plan for the year.

The group will review prior year QI findings and outcomes and any reported issues of non-compliance from the prior year, as well as identified opportunities for improvement.

The established plan will focus on quality, effectiveness, and efficiency of the HRPP program and processes. The annual plan will be posted of the HRPP website and disseminated to all IRB committee members. The plan will be implemented by the HRPP Compliance Coordinator and assigned staff with the support of the HRPP Director.

The conduct of the review process will be monitored monthly by the HRPP Director with quarterly reports to HRPP leadership and IRB Committee Chairs.

The plan will, at a minimum, contain:

a. The goals of the quality assessment/improvement plan with respect to measuring effectiveness, identifying opportunities for improvement, and achieving and maintaining targeted levels of quality, efficiency, effectiveness, and compliance.
b. And include at least:
    i. One objective to achieve or maintain compliance is defined,
    ii. One measure of compliance,
    iii. The methods to assess compliance and make improvements are described,
    iv. One objective of quality, efficiency, or effectiveness,
    v. One measure of quality, efficiency, or effectiveness,
    vi. The methods to assess quality, efficiency, or effectiveness and make improvement are described.

The results of the plan are reviewed quarterly by the HRPP Director, Institutional Official and IRB Chairs to identify trends, and to determine if local and/or systemic changes are required. Relevant participants will participate in the development of action plans, implementation, and evaluation of effectiveness.