Improving the Quality of the HRPP by Integrating Compliance, Quality Improvement, and Education

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Published In/Presented At

Lipkin, S., Gogel-Bissell, L., Sabella, V., Dreher, M., Phillips, J., Hoffman-Terry, M., & Scott, J. (2013, April). *Improving the quality of the HRPP by integrating compliance, quality improvement, and education.* Poster presented at: The Association for the Accreditation of Human Research Protection (AAHRPP) Annual Conference, Miami, FL

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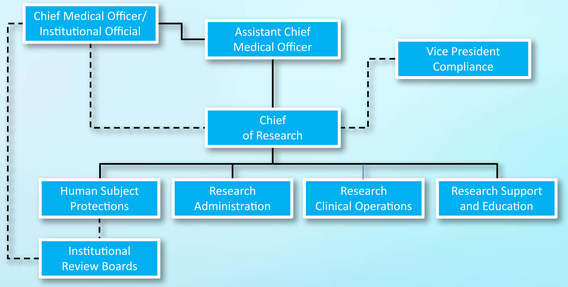
Lehigh Valley Health Network (LVHN), the largest academic community hospital system in Pennsylvania, has centralized its clinical research enterprise into one office named the Network Office of Research and Innovation (NORI). Centralization has resulted in integration and coordination of research operations throughout human subject protections, research clinical operations, research business administration, and research support services. This integration has, in turn, provided opportunities to enhance operational efficiencies while diminishing institutional research compliance exposure.

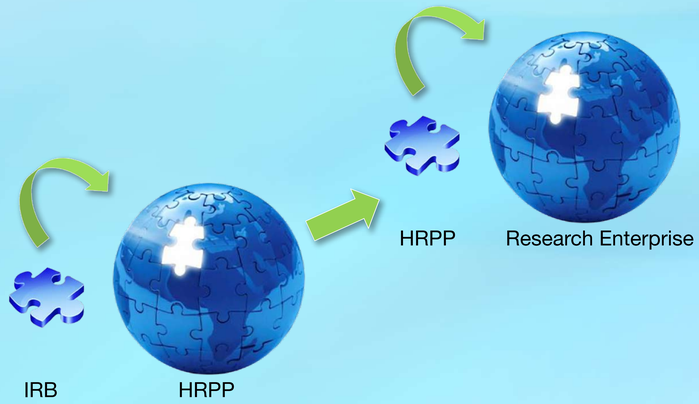
With centralization, NORI has integrated post-approval monitoring, quality improvement, and education throughout the entire research enterprise with a strong emphasis on human subject protections. This continuum of quality assurance, quality improvement, and education has been well received by the research community, who have embraced these activities as collegial and constructive in an environment of accountability and transparency.



Integrating human subject protections with the clinical research enterprise:

- Organizational structure
- Harmonized research approval process
- Institution wide feasibility review
- Centralization of research support services
- Clinical trial agreements
- Research compliance oversight
- Quality improvement
- Education

Evolution of the HRPP Concept



Research Compliance Oversight	Audit	Education
• Research compliance monitoring as a responsibility of the research office • Research compliance with strong emphasis on human subject protections • Research compliance committee maintains primary responsibility for FCOI and serious or continuing noncompliance --- provides management plan to IRB • Chief of Research "quarterbacks" resesarch compliance activities • Research compliance committee reports to Corporate Compliance Committee through the VP of Audit/Compliance	• Research Compliance Monitor conducts post-approval monitoring • Post-approval monitoring includes for-cause and routine audits • Auditing activities are collegial and educational • Research Compliance Monitor observes the informed consent process when direct by the IRB	• Core curriculum established by research directors • Additional content derived primarily from identified areas of risk and hot topics • Content written and delivered with a comprehensive perspective

Integration of Quality Assurance, Education, and Quality Improvement has resulted in improved GCP and Human Subject Protection Compliance:

For example, audit results of one NCI sponsored cooperative group showed a significant decrease in the number of major and minor violations after centralization of research and implementation of integrated QA-Education-QI over a 12 month period of time.