

disseminated to personnel in the Institute for Health Research (IHR). **Conclusions:** Several existing processes and resources were identified for use in the research context, however these were fragmented and difficult to access systematically. The toolkit brings together these existing processes and resources for member engagement and supplements them with additional principles for engagement. After further testing to understand the toolkit's contribution to project development and completion, it could serve as an example for other HMORN partners for development of similar resources.

Keywords: Patient-Centered; Stakeholder; Toolkit

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C1-1:

Portfolio Management: Using Lean Tools to Support Project Teams with Grant Management

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Background/Aims: Group Health Research Institute (GHRI) utilizes Lean tools and techniques to enhance customer service, monitor compliance, and enhance project team interactions and communications. GHRI's Grants and Contracts Administration (GCA) recently used Lean tools to design and implement a grant "portfolio management" system and process to support Principal Investigators (PIs). The system tracks six key indicators of funded grants: award status, budgetary spend rate, effort reporting, subaward execution, subawardee invoicing, and progress reporting. The process allows issues to be identified, tracked, and resolved early on with the project team before any serious problems arise. **Methods:** GCA conducted a series of stakeholder interviews to determine the viability of quarterly portfolio review meetings. Project teams liked the idea of discussing the PI's portfolio, but were leery about quarterly meetings. Therefore, we constructed a process that maximized technology and built in flexibility regarding quarter meetings. The six key indicators were selected, defined, and placed on a dashboard in SharePoint. Each PI has a customized SharePoint page with a calendar showing all major grant deadlines and deliverables; a folder of documents related to the rankings and discussion during each quarterly meeting; and an issue tracker to follow-up on team-identified issues and problems requiring attention. Customer satisfaction data was also collected after each initial quarterly meeting. **Results:** As of October 2012, approximately 25 face-to-face meetings and 5 virtual meetings (i.e., materials and links emailed to the project team) have been completed (210 projects and 85 subawards will have been reviewed by the end of 2012). Satisfaction survey data indicates over 75% of team members (22 of 30 individuals) like the face-to-face meetings and hope to continue the quarterly review process. **Conclusions:** The new portfolio management process has been received favorably by GHRI project teams as a means of monitoring key indicators of PI project portfolios and proactively identifying and resolving any problem areas.

Keywords: Grant Management; Compliance; Team Communication

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C1-2:

The Division of Research Comprehensive Clinical Research Unit Pre-Award Process and Budgeting for Clinical Trials

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Background/Aims: Launched in 2008, the Comprehensive Clinical Research Unit (CCRU) is charged with providing Kaiser Permanente Northern California (KPNC) research investigators pre-award services including industry and non-industry sponsored clinical trial budgeting and proposal preparation. The CCRU provides first-line communication for the Principal Investigator (PI) for feasibility review of study protocols, clinical trial budgets and clinical trial and sponsored research agreements. The purpose of this presentation is two-fold: (1) describe CCRU's comprehensive pre-award services and (2) describe the process and tools employed by the CCRU for developing and negotiating clinical trial budgets. **Methods:** The CCRU has implemented a pre-award service model in which the CCRU reviews and conducts a comprehensive feasibility assessment of proposed clinical trials, designs a clinical trial budget, directly negotiates the budget with the sponsor,

and concludes the budget process by approving (or rejecting) the budget and budget terms. The CCRU Lead Financial Analyst spearheads the budget development and negotiation, and works in tandem with the Revenue group for billing coverage analysis. Post-award functions and Clinical Trial Agreement (CTA) approval are under the auspices of KFRI's Grants and Contracts office. The CCRU employs a budget template, the Site Assessment Survey (SAS) which provides line-item delineations of pass-through costs, per-subject procedures costs, invoiceable charges, staff salaries, and overhead cost. Time and effort analysis, and standard versus research care determinations are performed with PI participation. Procedures costs are based on the most current KPNC Master Fee Schedule. **Results:** The pre-award program offers KPNC investigators a directed and streamlined approach to clinical trial budgeting and other clinical trials operations functions, and helps consolidate clinical research administration overall. The overall pre-award process has yielded more transparent and defensible budgets, conducted in a highly collaborative fashion, with input from the PI, the CCRU management team, Revenue group, and KFRI Grants and Contracts. **Conclusions:** The CCRU pre-award program provides high quality and timely clinical trial pre-award service that includes study feasibility analysis, Medicare Coverage Analysis, study budget development, and compliance, thus enhancing KPNC clinical research capabilities. The pre-award program is critical to the sustainability and growth of the KPNC research enterprise.

Keywords: Pre-Award Process; Clinical Trial Budgets; Billing Coverage Analysis

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C1-4:

Preparing for FDA Bioresearch Monitoring (BIMO) and Good Clinical Research Practice (GCP) Inspections: Fundamentals for KP Clinical Trial Sites

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Background/Aims: With over 300 FDA-regulated clinical trials currently open at Kaiser Permanente Northern California (KPNC), the need for a quality-based systems approach for managing clinical trials and preparing for FDA audit of these trials is paramount. Over the past five years, the FDA's Division of Bioresearch Monitoring (BIMO) has conducted, on average, 325 to 350 inspections of medical device clinical trials each year. In 2011, FDA issued warning letters to Sponsors, IRBs, and Clinical Investigators, citing numerous GCP violations involving pharmaceutical trials. Non-compliance findings ran the gamut; from violations related to required regulatory submissions to deviations from written procedures, and failures to maintain study documents. This presentation will: (1) discuss the triggers and types of FDA audit and the procedures necessary to prepare KP investigators and sites for a successful audit, and (2) discuss the approaches to ensure GCP and audit-readiness at all times. A case study of a routine BIMO audit of a KPNC study site participating in an investigational device trial will be presented. **Methods:** Prior to an FDA audit, a member of the Comprehensive Clinical Research Unit (CCRU) of the KPNC Division of Research routinely conducts a comprehensive site gap analysis to determine compliance issues or deficiencies in clinical research practices. A gap analysis includes reviewing records and procedures concerning interactions with the IRB; reviewing records and procedures concerning test article accountability, Adverse Event (AE) reporting, human subject protections, subject enrollment criteria; reviewing the facility and equipment; and verifying that data collected in Case Report Forms are supported by source documents. **Results:** Prior to the device BIMO audit at the KPNC site, we conducted a gap analysis of 100% of patient and research records to determine research compliance. The gap analysis allowed the study team to identify and correct deficiencies that would have otherwise increased the site's risk for unfavorable findings, and allowed the site to implement preventive actions to sustain high-level compliance. The site passed the audit successfully without a single citation from the FDA. **Conclusions:** Conducting a comprehensive pre-audit gap analysis and a quality-based systems approach to maintain optimal GCP compliance are essential to a successful audit.

Keywords: FDA Bioresearch Monitoring; Gap Analysis; Good Clinical Research Practice

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